Ministry of Commerce and Industry
Department of Commerce
Government of India

Strategy for Increasing Exports of Pharmaceutical Products

Report of the Task Force

December 12, 2008

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Acknowledgements

The Task Force to recommend measures for increasing exports of pharmaceutical products was constituted in July, 2006. As this Report would show, the Task Force has gone into the subject at length and instead of limiting its task to examining only the 'front end' of pharmaceutical exports it has dwelt deep into corresponding domestic policy linkages which would help in increasing exports as well. This increased the ambit of work undertaken by the Task Force. It was a privilege to have been associated with this task. I would not have been able to prepare this Report without receiving fullest cooperation from other members of the task force and inputs from various agencies such as Pharmexcil, Indian Drug Manufacturers Association (IDMA), Indian Pharmaceutical Association (IPA), Bulk Drug Manufacturers Association, Ayurvedic Drugs Manufacturers Association (ADMA) etc. Besides these agencies, Departments of the Government of India, namely, Department of Chemicals and Petrochemicals (now Department of Pharmaceutical), Department of AYUSH, National Medicinal Plants Board, Office of Drug Controller General of India, Department of Science & Technology and others were consulted, their inputs received and duly incorporated.

In this intense endeavour, I have been particularly assisted by Pharmexcil which is the export promotion council for pharmaceutical products, particularly its Executive Director, Dr. P.V. Appaji and his colleagues – to mention specifically Mr. P. Balram. This work would not have seen the light of the day, if I had not received most able and intensive contribution of facts, thoughts and suggestions from Mr. Lanka Srinivas – a distinguished expert on pharmaceuticals. He has been singularly responsible for responding to the roadmap which I had chalked out for deliberations and preparation of the Report. Mr. Srinivas deserves all my gratitude for his wholesome contribution to this exercise.

I have in the process of this exercise consulted a wide cross section of Indian pharmaceutical industry. Therefore, it is not possible to name everyone in this small piece of acknowledgement. However, some names need to be specially mentioned, such as Mr. Ranjit Puranik, and a few of his colleagues in the ADMA who gave very valuable inputs on the traditional medicine sector which in our opinion has tremendous potential for growth. I am intentionally not mentioning all those names whose contributions deserve to be acknowledged lest I miss out some others. Therefore, I would on behalf of the Task Force like to acknowledge with sincere gratitude their contribution in the preparation of this Report. While every effort has been made to ensure factual correctness and sources have been acknowledged, some inconsistencies and discrepancies are not ruled out. However, best efforts have been made to make this Report as comprehensive as we could within our limited capacities.

(Rajeev Kher)
Joint Secretary, Department of Commerce
Chairman, Task Force

Composition and Terms of Reference of the Task Force

Composition

1. Joint Secretary, Dept. of Commerce – Chairman
2. Director/ Dy. Secretary, EP (CAP) - Convener
3. Representative of Dept.of Chemicals & Petrochemicals
4. Representative of Dept. of AYUSH
5. Representative of Ministry of Finance
6. Representative of Ministry of External Affairs
7. Representative of Planning Commission
8. Representative of Trade Policy Division, Dept.of Commerce
9. Representative of National Medicinal Plants Board
10. Representative of Directorate General of Foreign Trade
11. Representative of O/o Drug Controller General of India
12. Chairman/ Executive Director, Pharmexcil
13. CEOs of some major Pharma industries

Terms of Reference:

i. To examine the problems being faced by the exporters of pharmaceutical products in consultation with the stakeholders and to prepare short-term, medium-term and long-term Action Plans.

ii. To review the progress of export of pharmaceutical products and suggest measures of achieving the growth targets.

iii. To act as 'Think Tank' and make appropriate policy recommendations for boosting exports and generating more employment in the sector.

iv. To consult the trade and industry and identify policy and procedural bottlenecks and suggest ways to eliminate them.

Executive Summary

The Indian pharmaceutical sector is emerging as one of the major contributors to Indian exports with export earnings rising from a negligible amount in early 1990s to Rs.29,139.57 crores (US$7.24bn) by 2007-08. The exports of Drugs, pharmaceuticals & fine chemicals of India have grown at a compounded annual growth rate (CAGR) of 17.8% during the five-year period 2003-04 to 2007-08. The Indian domestic pharmaceutical market size is estimated at US$10.76bn in the year 2008 and is expected to grow at a high CAGR of 9.9% percent till 2010 and thereafter at a CAGR of 9.5% till 2015.

However, this is still miniscule in comparison to the opportunity existing in the global market or with the exports cornered by major pharmaceutical exporting countries. The global pharmaceutical markets were estimated at US$712bn in the year 2007 growing at 6.4 percent. The market size of USA is estimated at US$295-305bn (growing at 4-5 percent) followed by Top 5 European countries (EU-5) with an estimated market size of US$135-145bn (growing at 4-5%), emerging markets, viz., Brazil, China, India, Mexico, Russia, South Korea & Turkey with an estimated market size of US$85-90bn. (growing at 12-13%) and Japan with an estimated market size of US$64-68bn (growing at 1-2%).

India is undisputedly an acknowledged leader in the global pharmaceutical industry (other than drug discovery) measured by any yardstick say number of facilities filing DMFs or facilities inspected by US FDA or number of patent challenges or volume of APIs & formulations exported, etc. In spite of considerable achievements, several untapped business segments and markets exist and the room to enhance the country's pharmaceutical exports is vast. The sophisticated chemistry capabilities, lateral thinking abilities in developing non-infringing processes, disciplined approach to adhere to any stringent guidelines, dedication for manufacturing excellence, etc., make India as a most favourite destination to source or outsource various components of value chain. Although various government institutions are working with great zeal to boost the industry, there exist multi-departmental issues arising out of globalisation and challenges, which need to be addressed. In addition, despite our success, we are still at the periphery of this vast opportunity.

A number of leading drugs go off patent every year and the generic pharmaceuticals penetration is increasing in all the countries of the world further raising the opportunity for exports in this segment. Approximately US$123 billion worth of generic products are at risk of loosing patents by 2012. Even at a conservative estimate of 15% opportunity, this translates into US$18.4 billion opportunity for India. Intense science, good understanding of patents and manufacturing to the stringent requirements of access regime are key requirements for future success in this opportunity. India has the requisite capabilities. Hitherto most opportunities emanated from synthetic chemistry. The opportunities in biopharmaceuticals will be the major attraction in the next decade. New technologies and enhanced regulatory requirements are changing the rules of the game making production migrate to east.

The global market for contract manufacturing of prescription drugs is estimated to increase from a value of $26.2 billion to $43.9 billion. India and China could potentially account for 35 percent to 40 percent of the outsourced market share for active pharmaceutical ingredients, finished dosage formulations and intermediates. Costs of clinical trials in India are around one-tenth of their levels in the U.S. and it is estimated that they could be worth US$300 million to India by 2010. There has been a great deal of interest in alternate remedies for some time now. World market for natural products is estimated at US$62 billion and is exhibiting double-digit growth rate.

India with its significant advantage of low cost of innovation, low capital requirements and lower costs in running facilities, well established manufacturing processes, R&D infrastructure, is strategically well positioned to emerge as 'Health Keeper' of the world. Third world countries are increasingly looking towards India as an alternative source for affordable medicines to solve their increasing healthcare costs. The recent antiretroviral revolution to help millions of aids patients in the world was possible only due to India, which is clearly acknowledged world wide.

Pharmaceutical industry can help India transform itself into a knowledge driven economy with firm routes in science and intricate knowledge of production and manufacturing engineering. The industry has risen in its importance from a sector to an important part of development process. The country has to look at pharmaceutical sector as a strategic & flagship industry. The Current success is due to amalgamation of R&D (developing non infringing processes and reverse engineering), manufacturing excellence (designing and running world class facilites with economies of scale), globalisation ability (establishing presence/ acquisitions/ mergers in the international markets). Such multidimensional excellence will make Pharma the torch bearer of the nation paying way for R&D led global market leadership in various goods and services.

Comparisons are some time drawn between the Information Technology/Information Technology-Enabled Services (ITES) and pharmaceutical industry to prove that state intervention and support may not be necessary as private sector is capable of spearheading itself. There is no doubt about the capacity of Indian pharmaceutical sector in taking the big leap forward. Comparisons with information technology will be mis-founded for several reasons. Primary among them are the fact that pharmaceuticals serve survival needs in all societies and traditionally the sector got its momentum from government policies, which developed its inherent strength. It may be necessary to note that pharmaceuticals all over the world are heavily regulated products.

India needs a very strong pharmaceutical industry if it has to provide affordable medicines to its over one billion population. The country with out strong drug discovery capabilities would be at the mercy of foreign pharmaceutical MNCs in the future for new & innovated drugs. The next decade is crucial in finding a

viable strategy to maintain the current dominance in chemistry, develop biology and to create drugs that could help the nation.

Today, the whole world acknowledges the supremacy of Indian pharmaceutical capabilities in chemistry, manufacturing and adhering to stringent guidelines of most advanced nations. In addition to generating revenues and securing appropriate medicines for its citizens, the pharmaceutical industry propels the country to emerge as a knowledge economy. Intricate science, technology, legal aspects and regulations involved in pharmaceuticals industry creates a great scientific and business tempo that propels the nation. The diffusion impact of such knowledge economy will help various sectors to think of global dominance following the example of pharmaceutical industry and would provide means and drive in such achievement. Due to excellent regulatory and fiscal climate, we have travelled a significant distance. India needs to protect what it has achieved, and draw key milestones, road maps and measure our success with conscious effort to emerge as an alternate power in the global health sector.

Government of India needs to more proactively nurture this sector by addressing the missing links and strengthening the policy environment to encourage industry to find its rightful place sooner than later. India is also exposed to the threat of takeovers from global big pharmaceutical companies under the new IPR regime. Indian pharmaceutical industry being fragmented with small balance sheet sizes; takeover by global pharmaceutical companies would adversely affect the health interests of the nation. Hence there is a case to promote internal consolidation and develop stronger companies that have width and depth in market access, manufacturing and R&D.

It may be recalled that Information Technology industry while emerging in the country produced some professionals who evolved to be world class leaders in Information Technology establishing Indian credentials in the sector. The emergence of these leaders helped in spear heading the Indian Information Technology industry globally. At the same time, these leaders had the charisma of consolidating and re-energizing not just the IT sector, but the new industry in India as a whole. In the pharmaceutical sector while some corporate entities have evolved as global leaders from developing countries, there is relative absence of individual pioneers, role models and leaders in the industry. It is not that they do not exist but their adequate projection with a view to consolidate the sector in the global context, position it at a platform of potential dominance and lead the sector from the front in order to catapult the sector into the higher orbit is lacking. It is, therefore, necessary that such icons need to be adequately recognized and projected as leaders of industry and consolidators of the sector.

There is another reason to contend that pharmaceutical industry deserves a greater focus today. A ‘brand India’ has gradually evolved around Indian pharmaceutical sector with the emergence of new segments of the industry, such as contract manufacturing, contract research services, bio-pharmaceuticals and Indian systems of medicines. It is even more necessary that this branding be

adequately strengthened. This would require investments in brand building. It is perceived that government needs to prepare an action plan for brand building around pharmaceutical sector. This will also help in creating several spin-off benefits such as for dealing with the problem of counterfeit drugs.

The Task force enunciated a vision for Indian pharmaceutical R&D as:

- "*To provide intellectual capital to make available safe, cost-effective, contemporary, quality therapeutics to the people of India and help reduce percentage of mortality and morbidity while emerging as a significant player in the global market place*."

- In consonance with this vision, a grand dream for production, export and investment in pharmaceutical R&D was evolved. This report suggests the measures by which such a dream and vision could be realised.

- Priority areas for Indian pharmaceutical R&D have been identified. India's expertise in developing new and innovative processes for known molecules needs to be exploited in a greater measure. While India forged ahead in conventional pharmaceutical technologies, it lagged behind in complex technologies, specialty pharmaceuticals and new drug delivery systems. Investment impetus required in these areas has been specified.

- Priority needs to be given for initiation of new drug development for diseases of relevance to the Indian population, while at the same time seizing opportunities to become a global player by introducing globally competitive products based on new molecules. Currently India is at a nascent stage in drug discovery and the industry is focusing on strategies to earn while learn. Key building blocks in the value chain could be focused to facilitate the drug discovery. These have been discussed.

- A key factor to retain competitiveness is low cost of innovation and process management. In the current context of rapidly rising wages for select skilled population, efforts to widen the skill base and strategies to generate the skill base have been discussed.

- To achieve such objectives, the existing human resources in conventional methods of drug discovery need refurbishing alongside acquisition of newer tools of drug discovery. A larger team of experts comprising chemistry, biology, biotechnology, etc., need to find select viable strategies for India in drug discovery. Drug discovery is a product of strong efforts at universities, public institutions and industry. The direction of effort has been specified.

- Citing the unique opportunity for India to become a leading centre for clinical trials, the report suggests basic changes in the legislation allowing import of animals, contract research and a legal status for institutional animal ethics committee. Establishment and operationalisation of a cGMP, GLP and GCP monitoring authority has been recommended.

- Recognising the crucial role played by the Indian systems of medicine in the health care needs of world population, the Task Force has recommended initiatives to strengthen and modernise the existing infrastructure. Proper scientific documentation of India's traditional knowledge base in the internationally accepted format and media has been suggested as a priority. For any industry to succeed and become globally competitive a strong home market is essential. Certain initiatives have been specified to foster the progress of the industry.

- A higher level of innovation and IPR management coupled with strategic manufacturing and aggressive marketing will largely determine Indian pharmaceutical industry's future. Specific measures for strengthening the IPR system with action points for the Government, judiciary and the legal system, industry, Department of Science & Technology and educational system have been suggested. Some suggestions for enacting a TRIPS compatible IPR legislation, which protects the interest of the consumers and allows a platform for the growth of Indian pharmaceutical industry, have been made.

- This Report identifies concrete action points for various stakeholders, particularly the government agencies and departments over the next few years. The expanse of recommendations is wide and deep. It ranges from action in the sphere of linkages to be sought between academics, research and industry; evolving a new regulatory regime in view of emerging concerns of the industry in its multi-faceted dimension; mechanisms for coordination on a multi-disciplinary platform; the front end of export policies and incentives required to facilitate exports; capacities both at the scientific level within the industry and at regulatory and administrative level for developing the industry; identifying infrastructure required for the purpose, etc. The section on key recommendations summarizes the discussion in the previous sections to give concrete suggestions. Further a role analysis of promotional institution such as Pharmexcil has been carried out and recommendations made

1. Introduction

The pharmaceutical sector is one of India's most important sectors in terms of projected revenue growth from exports and for meeting the needs of Indian population. There are a larger number of markets to which Indian pharmaceutical companies can now export as a result of global trade liberalisation and capacity building by Indian companies over the last decade. India, considered as a knowledge intensive economy, is looked upon to make available drugs that are affordable to the developing countries. The recent contribution of Indian generics in fighting AIDS and its contribution to affordable healthcare in US and elsewhere is widely acknowledged.

1.1 Mandate, Methodology and Analysis

1.1.1 Mandate

Department of Commerce, Government of India decided to constitute a Task Force on pharmaceutical exports to suggest measures for boosting exports in a sustainable manner. Accordingly, a Task Force was constituted under the Chairmanship of Joint Secretary, Department of Commerce, incharge of Pharmaceutical exports, vide Office Order No.13/6/2006-EP (CAP), dated 18th July, 2006. The report of the task force has been delayed inordinately. The reasons are not far to seek. The mandate of the task force was as follows:

(i) To examine the problems being faced by the exporters of pharmaceutical products in consultation with the stakeholders and to prepare short term, medium term and long term action plans.

(ii) To review the progress of exports of pharmaceutical products and suggest measures of achieving the growth targets.

(iii) To act as "Think tank" and make appropriate policy recommendations for boosting exports and generating more employment in the sector.

(iv) To consult the trade and industry and identify policy and procedural bottlenecks and suggest ways to eliminate them.

It was soon realised that an analysis of measures pertaining to foreign trade policy alone would have only touched the surface of the challenges facing a sector which has the greatest potential for growth. Moreover prospects of increasing exports are very intimately related to the challenges faced by the sector at home and unless some of them are examined, the committee would only have done partial justice to its mandate. The task force had a clear conviction about the connect between the domestic environment in which the sector works and its impact on export prospects. The last two terms of reference in any case required interaction with a wide cross section of the sector. This realisation led the task force to carry out a wider interaction with the stakeholders particularly with the experts in the industry and all this lead to unusually long time.

1.1.2 Methodology

The Task Force has primarily used consultative process in formulating this paper and the data for the same has been gathered through various structured and unstructured meetings among representatives of Department of Commerce, Government of India, Department of Chemicals and Petrochemicals including the newly constituted Department of Pharmaceuticals, Director General of Foreign Trade (DGFT), Department of Ayurved, Unani and Siddha medicine and various institutions such as Indian Drug Manufacturers Association (IDMA), Pharmaceutical Export Promotion Council (Pharmexcil), Ayurvedic Drug Manufacturers Association (ADMA), National Medicinal Plants Board (NMPB), etc., and various inputs, research reports and statistics provided by members of Pharmexcil, and other industry experts. In order to carry out consultations with industry experts many unstructured discussions were organised by the chairman of the task force and representatives from the industry have given wholehearted participation.

This report seeks to discuss separately various segments of pharmaceutical industry such as Generic Pharmaceuticals, Contract Manufacturing, Drug Discovery and Contract Research Services and Indian System of Medicines because of the distinct nature of the problems that require to be addressed by each of these broad areas. Within each area, this report seeks to address, the challenges faced by domestic industry and suggest initiatives to be taken by Govt. of India. Whereas the report tries to address most of the issues which were brought before it by stakeholders and were considered significant by the taskforce, there is a likelihood of some of the issues having been missed out. In most cases it could be because of inter-se prioritisation leaving out the lesser of the issues to save on space and maintain the focus.

2. Indian Pharmaceutical Sector - Current Status

2.1 Background

The Indian pharmaceutical industry can be said to have begun with the setting up of 'Bengal Chemical and Pharmaceutical Works' in Calcutta. Subsequently institutes like Kings Institute of Preventive Medicine in Chennai, Pasteur Institute in Coonoor, the Central Drug Research Institute in Kasauli and others were set up. Post-independence, many other public sector companies such as Hindustan Antibiotics Ltd. and Indian Drugs and Pharmaceuticals Ltd. were set up to reduce the imports of important antibiotics and also to meet the county's demand from indigenous production.[1]

The industry is conspicuous by the large presence of private sector which has captured a substantial share in the domestic & external market due to factors such as conducive regulatory environment, past patent policies, low cost of innovation, access to funds from banks to corporate manufacturers, low cost of setting up and running high technology manufacturing facilities, etc. The public sector as in many other sectors contributed to strategic areas but has gradually been overtaken by the private players – an indication of the latter's emerging competitiveness and entrepreneurial capabilities. Indian owned firms currently account for 70 percent of the domestic market, up from less than 20 percent in 1970. In 2005, nine of the top 10 companies in India were domestically owned, compared with just four in 1994.

Today, the pharmaceutical industry manufactures the entire range of therapeutic products and is capable of producing raw materials for the manufacture of a wide range of drugs from the basic stage as well as a range of pharmaceutical machinery and equipment.

Apart from building up domestic capacity, leading Indian companies have established marketing and manufacturing activities in a large number of countries including USA and countries of Europe as well as expanded through acquisitions in these countries.[2] The sector has therefore evolved from being dominated by multinational companies in the 1950's to some imports and indigenous manufacturing in the 1970's and then protected by the legislative provisions of the older Patents Act 1970, to significant indigenous production and subsequent exports.

[1] The industry was given its due by the successive governments in Indian Five year plans and the industry was promoted through direct investment, intellectual property, price regulation and above all the support of scientific research. Ashok Ram Kumar, *TRIPS - Is it a Healthy Prescription for Indian Pharmaceutical Industry*, 2(3) THE ICFAI JOURNAL OF INTELLECTUAL PROPERTY RIGHTS 71, 71 (2003).

[2] See The Economist, "Marauding Maharajas", March 29th, 2007.

The expertise that the Indian pharmaceutical sector developed in reverse engineering and production of generics can be directly attributed to the effects of Governmental policy such as the Patents Act, 1970 which played a major role in shaping the industry and bringing it to the present enviable position. The Act of 1970 excluded product patents on pharmaceuticals, allowing the mushrooming of a vigorous generics industry in India which could meet not only domestic demand for drugs at lower prices but could also export cheaper drugs to other Third World countries.[3] Further, the government policies restricted imports of finished formulations, imposed high tariff rates and introduced strict price control regulation through the 1970 Drugs Price Control Order.

Post liberalization, the pharmaceutical industry has had to reorganize itself to keep pace with the economic reforms as well as the international commitments that were taken on by India. From a regulatory perspective, a large degree of liberalisation took place with the abolition of industrial licensing, 100 percent foreign direct investment, liberalisation of rules related to foreign technology agreements as well as of the import regime. At the same time, international commitments and standards were sought to be introduced into the regulatory regime through the introduction of product patents, the introduction of Schedule M and Schedule T of The Drugs and Cosmetics Act, 1940. Export promotion was sought to be encouraged by the creation of PHARMEXCIL as well as a draft National Pharmaceuticals Policy, 2006 with the objective of, among other things, positioning India as a preferred global destination for pharmaceutical R&D and manufacturing. The recent creation of a separate Department of Pharmaceuticals is only a manifestation of the importance government of India has accorded to the sector.

The new patent regime has also led to the return of the pharmaceutical multinationals, many of which had left India during the 1970s. The multi-national companies are now looking at India not only for its traditional strengths in manufacturing but also as a highly attractive location for research and development (R&D), particularly in the conduct of clinical trials and other services. The consumption potential offered by more than one billion inhabitants, rising affluent customers and the changing lifestyles offer huge potential domestically for the sector.

[3] Shamnad Basheer, *Policy Style Reasoning at the Indian Patent Office*, 2005 INTELLECTUAL PROPERTY QUARTERLY 309.

2.2 Current Status

The pharmaceutical sector is emerging as one of the major contributors to Indian exports with export earnings rising from a negligible amount in early 1990s to Rs.29,139.57 crores by 2007-08. The exports of Drugs, pharmaceuticals & fine chemicals of India were growing at a compounded annual growth rate (CAGR) of 17.8% during the five year period 2003-04 to 2007-08.

The total size of the industry is estimated at US$18bn at the end of the year 2007. The Indian domestic pharmaceutical market size is estimated at US$10.76bn in the year 2008 and is expected to grow at a high CAGR of 9.9% percent till 2010 and thereafter at a CAGR of 9.5% till 2015.

Currently, the Indian pharmaceutical industry is one of the world's largest and most developed, ranking 4th in volume terms and 13th in value terms. The country accounted for 8 percent of global production and 2 percent of world markets in pharmaceuticals. Most of the domestic pharmaceutical drug requirements are met by the domestic industry. In the segment of Active Pharmaceutical Ingredients (APIs) India ranks third in the world producing about 500 different APIs.

2.2.1 Current Place in World

India is currently recognised as a high-quality, low-cost skilled producer of pharmaceuticals. It is seen not only as a manufacturing base for APIs and formulations, but also as an emerging hub for biotechnology, bioinformatics, contract research, clinical data management and clinical trials. The country's pharmaceutical industry, as evidenced in the paragraphs which follow, has shown tremendous progress in terms of infrastructure development, technology base creation and a wide range of production.

India exports full basket of pharmaceutical products comprising intermediates, APIs, Finished Dosage Combinations (FDCs), biopharmaceuticals, vaccines, clinical services, etc., to various parts of the world. The country has achieved the distinction of providing healthcare at very low cost while maintaining profitability.

At present, India is among the top 20 pharmaceutical exporters world-wide and with the largest number of US FDA inspected plants (119 plants), outside the USA. Various other agencies like MHRA UK, MCA South Africa, TGA Australia , HPB Canada have approved scores of plants in India .

India accounts for over one third of drug master files (DMFs) in USA. (Refer Tables & Charts-1, 2, 3 & 4 and Appendix I for list of Indian companies having active type II DMFs with US FDA). Thirty percent of all approved ANDAs in the US are from India, ranking the country number 2 next only to USA. Needless to mention scores of approvals by UK MHRA and various other agencies are also being filed from India.

Even in patent challenges, India ranks only next to USA with a share of 21 percent of patent challenges. Undeniably India is an emerging leader in pharmaceuticals.

Table 1: Final ANDA Approvals by Country (2007) (figs. in Nos.)

Country	Numbers
USA	169
India	132
Israel	40
Germany	25
Canada	24
Switzerland	19
Iceland	14
Jordan	11
Other	25

Source: Thomson Scientific,

Table 2: Country-wise Number of Patent Challenges (As on Mar. 2008)

Country	Numbers
USA	200
India	113
Israel	89
Canada	43
Switzerland	34
Iceland	17
Germany	10
Other	32

Source: Thomson Scientific

Table 3: Comparison of Drug Master Filings (Type II) by India, China & World (1998-2007) (Figs. Nos.)

Year	India	China	World Total
1998	32	27	316
1999	26	6	199
2000	33	9	201
2001	47	6	238
2002	55	20	264
2003	115	19	360
2004	160	25	435
2005	233	70	615
2006	267	78	627
2007	274	90	656

Source: Thomson Scientific

Table 4: FDA Approved Indian API Facilities

Year	Annual	Cumulative
1985	0	0
1990	1	1
1995	10	11
2000	33	44
2005	75	119

Source: Thomson Scientific

2.2.2 Current Status of Generic Biopharmaceuticals

Fermentation, one of the segments of biotechnology, has been instrumental in shaping Indian antibiotics segment in the early decades of growth of Indian Pharmaceutical industry with remarkable contribution from Hindustan Antibiotics Ltd. (HAL), Sarabhai group, and a few others. However, due to lower energy costs in China in the past, fermentation industry has moved to China not only from India but also from several other countries.

Vaccines, large molecules, monoclonal antibodies and recent therapeutics demand significant capabilities in chemistry and biology. IMS Health estimates that biotechnology products accounted for over 10 percent of global pharmaceutical sales. A significant portion of new drugs in the recent years are from biopharmaceuticals segment. The revival of this once strong sector seems to have begun in India as is witnessed by the success of some of the emerging players such as, Serum Institute, Biocon, Panacea Biotech, Venkateswara Hatcheries, Wockhardt, Shanta Biotech, Bharat Biotech, etc.

2.2.3 Impressive Investments in Capacity Building and Capabilities

The combined total investment (Gross Block) of 561 pharmaceutical companies listed on Bombay Stock Exchange as per the latest company filings available (as at the end of June 2008) stood at Rs.40,461.7 crores (net fixed assets stood at Rs.29,325crores). Further, as per Centre for Monitoring Indian Economy (CMIE) database 'Capex,' an investment of Rs.5,903.1 crores in some 550 projects under implementation and new investment projects in 637 new proposals announced valued at approx. Rs.5,861.8 crores would result in the new investment of Rs.11,764.9 crores, which is an increase of 29 percent over the existing investment. Some major projects under implementation or announcement are given at Appendix II.

2.2.4 Research & Development

Data for 596 Indian pharmaceuticals companies, whose sales and R&D investment figures are available with CMIE database 'Prowess', reveals that a total of 151 companies invested in R&D activities as at the end of June 2008 (Refer Table 12 & chart 12). The total investment in R&D stood at Rs.2,973.2 crores which is 9.9 percent of the sales of these 151 companies. (Refer Appendix III).

Nevertheless, the domestic industry is still spending far too little on basic R&D, which may not increase substantially due to the size of their balance sheets and profitability and hence the requirements of the drug discovery remain unaddressed.

Table 5: Investment by Top 20 Indian Pharmaceutical Companies* (figs. in Rs. Crores)

Sl. No.	Company Name	Sales	Research & development expenses	Investment in R& D as % of Sales
1	Ranbaxy Laboratories Ltd.	3,656.2	460.5	12.6
2	Dr. Reddy's Laboratories Ltd.	4,146.2	292.8	7.1
3	Sun Pharmaceutical Inds. Ltd.	1,722.1	188.3	10.9
4	Cipla Ltd.	3,658.0	175.7	4.8
5	Cadila Healthcare Ltd.	1,758.5	161.8	9.2
6	Lupin Ltd.	2,051.7	142.1	6.9
7	Wockhardt Ltd.	1,189.0	126.7	10.7
8	Torrent Pharmaceuticals Ltd.	895.2	112.1	12.5
9	Panacea Biotec Ltd.	843.0	107.2	12.7
10	Aurobindo Pharma Ltd.	1,991.0	96.7	4.9
11	Matrix Laboratories Ltd.	775.7	92.1	11.9
12	Orchid Chemicals & Pharmaceuticals Ltd.	934.2	63.0	6.7
13	U S V Ltd.	659.2	59.6	9.0
14	Ind-Swift Laboratories Ltd.	356.1	58.5	16.4
15	Biocon Ltd.	887.2	47.9	5.4
16	Glenmark Pharmaceuticals Ltd.	838.8	43.3	5.2
17	Strides Arcolab Ltd.	395.2	37.5	9.5
18	Dabur Pharma Ltd.	322.0	35.7	11.1
19	Piramal Healthcare Ltd.	2,001.3	35.3	1.8
20	Alembic Ltd.	722.6	34.5	4.8

Source: CMIE database 'Prowess'

2.4.5 Health Tourism and Services

The health tourism market in India was estimated at US$333 million in 2004, growing by about 25 percent and this is predicted to become a US$2 billion-a-year business opportunity by 2012. India is witnessing a surge of patients from developed countries as well as from Africa, South & West Asia because while the cost of comparable treatment in India is about 1/8th to 1/5th of the cost in the Western countries, the quality of Indian healthcare delivery (in certain institutions) is world class. An added impetus has come from expanding health care budgets in developed countries due to rising costs of healthcare in these countries and increasing old age population. This challenge also offers us an opportunity to extensively upgrade our tertiary level of health care infrastructure. This report has not looked into this issue at greater length as the subject would be better studied under tourism sector.

3 Pharmaceutical Sector - Recent Trends

3.1 Global Pharmaceutical Market Trends

The global pharmaceutical markets were estimated at US$712bn in the year 2007 growing at 6.4 percent over 2006 (Refer table 5 & Chart 5). The global pharmaceutical industry has grown at a compounded annual growth rate (CAGR) of 10.7 percent for the period 2002-07.

Table 6: Global Pharmaceutical Market Size & Growth Rates (2000 to 2007) (figs. in US$ bn., & %)

Global Sales (US$ bn.)/ Year	2000	2001	2002	2003	2004	2005	2006	2007
Total World market (current US$)	365	392	428	499	560	605	649	712
Growth Over Previous year (constant US$ Growth)	11.50%	11.80%	9.50%	10.30%	8.00%	7.30%	7.10%	6.40%

Source: IMS Health Market Prognosis (includes IMS Audited and Unaudited markets)
All information current as of March 28, 2008

The market size of USA is estimated at US$295-305bn with an estimated growth rate of 4-5 percent. It is followed by Top 5 European countries (EU-5) with an estimated market size of US$135-145bn growing at 4-5%, emerging markets VIZ., Brazil, China, India, Mexico, Russia, South Korea and Turkey with an estimated market size of US$85-90bn. (growing at 12-13%) and Japan with an estimated market size of US$64-68bn (growing at 1-2%). The pharmaceutical market size of the rest of the world (ROW) is estimated at US$125-135bn which is estimated to grow at 7-8 percent in the coming years (refer table 6 & chart 6).

Table 7: Sales Through Retail Pharmacies (Twelve months to May 2008*)

Sl. No.	Region/Country	Market Size US$ bn.	Growth Rate
1.	NORTH AMERICA	223.3	2%
1a.	United States	206.5	4%
1b.	Canada	16.7	6%
2.	EUROPE (Top 5)	114.3	4%
2A.	Germany	34.4	7%
2b.	France	30.8	4%
2c.	United Kingdom	17.1	0%
2d.	Italy	16.9	0%
2e.	Spain	14.8	7%
3.	JAPAN (including hospitals)	63.2	5%
4.	LATIN AMERICA (Top 3)	23.2	9%
4a.	Brazil	11.6	10%
4b.	Mexico	8.7	6%
4c.	Argentina	2.8	21%
5.	AUSTRALIA/NEW ZEALAND	7.8	13%

Source: IMS Health

The global data on pharmaceutical market sizes and growth rates suggest that while protected markets such as US and Japan, account for major chunk of the global market, these are growing at a slow rate of 4-5% or even stagnant as in the case of UK & Italy. Spain, Germany and Canada on the other hand are huge and are growing between 6-7 percent. Argentina, Australia and Brazil are amongst the high growth markets. The size & growth rate of various therapeutic segments are presented in table 8 & Chart 8 and major exporting countries of the world are presented in table 7 & chart 7 below.

Table 8: Global Pharmaceutical Exports by Major Countries (figs. in US$ bn.) (2006)	
Germany	44
Belgium	38
Switzerland	31
USA	29
UK	26
India	7.2
Source: WTO	

Further, it can be noticed that the global pharmaceutical market is highly fragmented with top 22 companies accounting for only US$50bn which is 7% of total pharmaceutical sales and is highly competitive (refer Table 8 & Chart 8 for various major global pharmaceutical companies and their total sales.).

Table 9: Selected Global Generics Players 2007E Total Sales (figs. in US$ bn.)	
Company	**US$ bn**
Teva	$9.1
Sandoz	$5.8
Mylan/Merck GX	$4.6
Watson Andrx	$2.7
Barr	$2.5
Actavis	$2.1
Ratiopharm	$2.1
Stada	$2.1
Ranbaxy	$1.7
Perrigo	$1.5
Dr. Reddy's	$1.4
Apotex	$1.1
Cipla	$1.0
Krka	$1.0
Abraxis	$1.0
Gedeon Richter	$0.9
Sun/Taro	$0.9
Zentiva	$0.9
PAR	$0.8
Source: Capital IQ, Evaluate Pharma & Deutsche bank Report	

Of late, due to market compulsions for price efficiencies through economies of scale, necessity for huge investments in R&D, high entry barriers as a result of high cost of product registrations in multiple countries, increasing patent protection, increasing disposable incomes, etc., pharmaceutical industry across the globe has witnessed high-levels of mergers & acquisitions. (Refer table 9 & chart 9)

Table 10: M&A Activity in the Worldwide Generic Market (figs. in US$ mn.)

Year	US$ mn
2000	1,438
2001	1,025
2002	1,112
2003	3,083
2004	1,411
2005	20,056
2006	6,901

Source: Company fillings, Wall Street Research, UBS Investment Bank Report (includes only limited major activities)

3.2 Trends in Indian Pharmaceutical Industry

The Indian retail pharmaceutical market size is estimated at US$7.8bn in the year 2008 (refer Table 10 & chart 10) and is expected to grow at a high CAGR of 9.9 percent till 2010 and thereafter at a CAGR of 9.5 till 2015.

Table 11: Estimated Indian Retail Pharmaceutical Market size (US$ Bn)

Year	US$ bn.
2002	3.7
2003	4.1
2004	4.7
2005	5.3
2006	6.2
2007	6.9
2008	7.8
2009	8.7
2010	9.9
2011	11.1
2012	12.2
2013	13.4
2014	14.6
2015	16.0

Source: EIU Report, Datamonitor, primary interviews, Deloitte Consulting LLP analysis

The domestic industry is fragmented with top 10 companies capturing 30 percent (refer table 11 & chart 11) and the organized sector constituting over 500 companies. The total size of the industry is estimated at US$18bn at the end of the year 2007.

Table 12: Global Sales of Leading Indian Companies (2006-07) (US$ mn.)	
Dr Reddy's*	1,438.4
Ranbaxy**	1,405.2
Cipla	759.8
Nicholas Piramal	546.2
Sun Pharma	471.1
Aurobindo Pharma	437.5
Lupin	435.5
Wockhardt***	419.8
Zydus Cadila	394.6
Matrix***	364.2
Glenmark**	274.5
Orchid^	206.4
Source: Pharma Outlook, Espicom, 2008, ** Total Revenue, ** From Qrtrly statements, *** Net Revenue*	

3.3 India's Pharmaceutical Export Profile

Pharmaceutical industry has shown commendable export performance, the trade balance being positive through out the years. Over the period 2003-04 to 2008-09 the compounded annual growth rate (CAGR) of exports has been 17.8 percent. (Refer Tables & Chart s 13 & 14).

Table 13: India's Trade in Pharmaceutical Products (2003-04 to 2007-08) (figs in Rs. Crores & %)						
Commodity Name	**Mar-04**	**Mar-05**	**Mar-06**	**Mar-07**	**Mar-08**	**CAGR (2003-04 to 2007-08)**
Exports of Drugs, pharmaceuticals & fine chemicals	15,213.24	17,857.80	22,115.72	26,895.18	29,139.57	17.8
Imports of Medicinal & pharmaceutical products	2,958.04	3,169.35	4,550.87	5,851.64	6,679.87	18.4
Exports Growth Rate	18.61	17.38	23.84	21.61	8.34	
Imports Growth Rate	3.24	7.14	43.59	28.58	14.15	
Source: DGCI&S						

Table 14: India's Trade in Pharmaceutical Products (2003-04 to 2007-08) (figs in US$ mn. & %)						
Commodity Name	**Mar-04**	**Mar-05**	**Mar-06**	**Mar-07**	**Mar-08**	**CAGR (2003-04 to 2007-08)**
Exports of Drugs, pharmaceuticals & fine chemicals	3,312.99	3,972.81	4,994.52	5,939.75	7,241.44	22.2
Imports of Medicinal & pharmaceutical products	644.17	705.08	1,027.75	1,292.32	1,660.01	22.9
Exports Growth Rate	24.76	19.92	25.72	18.93	21.91	
Imports Growth Rate	8.59	9.46	45.76	25.74	28.45	
Source: DGCI&S						

The composition of Indian pharmaceutical exports during the years 2003-04 to 2006-07 are given in the table 15 & Chart 15:

Table 15: India's Exports of Bulk Drugs, Formulations, Ayurvedic, Unani, Homeo & Herbal Products (figs. In Rs. Crores)						
Commodity Name	**Mar-03**	**Mar-04**	**Mar-05**	**Mar-06**	**Mar-07**	**Mar-08**
Exports of Formulations	5,952.93	7,481.45	9,066.94	10,829.55	14,382.55	16,647.36
Exports of Basic Drugs, Fine Chemicals & Intermediates	2,493.36	7,207.79	8,091.69	10,740.51	11,868.29	13,299.33
Exports of Herbals	390.79	318.44	293.63	307.48	377.02	470.73
Medicants & Medicaments of Ayurvedic System	743.88	192.75	399.82	233.07	259.54	321.44
Medicants & Medicaments of Homeopathic System	8.19	10.30	2.11	1.87	2.74	3.05
Medicants & Medicaments of Unani System	0.00	2.08	1.89	1.13	0.70	1.13
Medicants & Medicaments of Siddha System	0.00	0.42	0.47	0.30	0.02	0.42
Source: DGCI&S						

3.3.1 Major Importing Countries from India

As of 2007-08 the large markets for Indian pharmaceutical exports & suppliers of pharmaceutical products to India are presented in the tables 16, 17 & charts 16 & 17 below:

Table 16:Top Importing Countries of Drugs, Pharmaceuticals & Fine Chemicals (2007-08) (figs. in Rs. Crores)

Rank	Importing Country	Rs. Crores	% Share in India's Exports
1	USA	5,534.68	19.1
2	Germany	1,357.72	4.7
3	Russia	1,199.02	4.1
4	UK	1,077.72	3.7
5	China	818.46	2.8
6	Brazil	752.62	2.6
7	Canada	738.03	2.5
8	South Africa	650.35	2.2
9	Nigeria	644.08	2.2
10	Netherlands	504.17	1.7
11	Spain	485.88	1.7
12	Turkey	485.47	1.7
13	Ukraine	475.88	1.6
14	Viet Nam	466.07	1.6
15	Israel	430.83	1.5
16	Italy	428.16	1.5
17	Mexico	426.28	1.5
18	UAE	412.13	1.4
19	Singapore	401.23	1.4
20	Iran	366.21	1.3

3.3.2 Major Exporting Countries to India

As of 2007-08 the source countries for Indian pharmaceutical imports of India are presented in the tables 17, 18 & charts 17 & 18 below:

Table 17: Top Exporting Countries of Medicinal & Pharmaceutical Products to India (figs. in Rs. Crores & %)

Rank	Exporting Country	Rs. Crores	% Share in India's Exports
1	China	2,760.90	40.7
2	Switzerland	912.13	13.4
3	USA	658.14	9.7
4	Germany	391.66	5.8
5	Denmark	287.03	4.2
6	Italy	208.25	3.1
7	France	194.82	2.9
8	UK	160.79	2.4
9	Belgium	124.59	1.8
10	Spain	117.44	1.7
11	India	102.37	1.5
12	Ireland	93.36	1.4
13	Japan	83.09	1.2
14	Korea Republic (South)	72.11	1.1
15	Netherlands	68.18	1.0
16	Austria	47.80	0.7
17	Indonesia	43.47	0.6
18	Poland	34.20	0.5
19	Mexico	31.03	0.5
20	Thailand	26.41	0.4

Source: DGCI&S

Apart from these, some of the fast emerging markets (2005-06) are presented in table 18:

Table 18: Countries of High Import Growth Rates in Pharmaceutical Products from India (2005-06) (figs. In Rs.Crores)

Country	Export Value	Growth%
South Africa	442.18	104.0
Israel	310.33	84.2
Turkey	426.22	78.5
Kenya	227.74	78.3
Singapore	378.50	58.5
UK	820.63	40.0
China	762.55	40.0
Russia	1,051.12	35.8
Italy	411.98	35.4
Vietnam	400.69	31.3

Source: WTO

3.4 SWOT Analysis of the Pharmaceutical Industry

Preceding sections make an effort to place Indian Pharmaceutical industry in the global perspective, followed by an examination of the trends in growth of industry both in terms of the emerging markets and products; and also the trends in global competition. It may be useful now to present a SWOT analysis of Indian Pharmaceutical Industry[4]:

3.4.1 Strengths

1. India is regarded as having an edge over China in terms of qualified, English-speaking manpower and fair protection of intellectual property rights supported by well-developed judicial system. (Appendix IV gives more information on IPR status in India).

2. India has skilled scientists/technicians/management personnel at affordable cost leading to low cost of innovation/ manufacturing/capex costs/ expenditure to run cGMP compliance facilities and high quality documentation and process understanding.

3. The country has well developed chemistry, R & D and manufacturing infrastructure with proven track record in advanced chemistry capabilities, design of high tech manufacturing facilities and regulatory compliance.

4. The healthy domestic market with rising per capita expenditure is another significant strength enabling achievement of economies of scale. The country also has a strong marketing & distribution network.

5. India is considered a desirable destination for off shoring of data management functions for clinical trials and also due to its rich biodiversity and strength in Chemistry which are essential for drug discovery.

6. The country has significant ability to circumvent API Patents. India has filed a number of non-infringing process patents. The country has a recent success track record in circumventing formulation patents. Proven Legal skills to evaluate IP and commercial strategies are available at least in select top companies.

[4] on the basis of statistics and perceptions founded on empirical evidence

7. The present domestic regulatory environment though in need of further improvement has been conducive to the growth of an emerging pharmaceutical industry.

3.4.2 Weaknesses

1. Low investments in innovative R&D continue to be a major weakness of Indian pharmaceutical industry.

2. Diffused nature of the Indian pharmaceutical industry means that only about 20 to 30 companies are large enough to bear the transactions costs associated with sustained exports to and compliance with entry regulations of the developed markets.

3. Majority of companies lack the ability to compete with MNCs for New Drug Discovery, Research and commercialization of molecules on a worldwide basis due to lack of resources.

4. Strong linkages between industry and academia which are essential for growth of the industry is lacking in India.

5. Comparatively small domestic market size due to low medical and healthcare expenditure in the country.

6. The country has at times shown inadequate regulatory framework or compliance and enforcement regime, reflected in occurrences such a production of spurious or low quality drugs.

7. Competency in API/Formulation, intellectual property creation, facility design and maintenance, global regulatory affairs, legal intricacies, and managing international work force is limited to a few players among the big players.

8. Rapidly increasing costs of skilled manpower such as scientists/ regulatory compliance personnel / pharmaceutical lawyers/ international business development personnel is pushing up the cost of innovation. Ability to evaluate contracts/alliances etc., is available only in top companies. Significant lacuna in this area exists and companies are falling into traps created by the competitors.. Institutionalisation of learning in the following areas is restricted:
   - Regulatory affairs knowledge for different countries and continents
   - Process and product patents procedures knowledge for different countries and continents.

9. Sales and marketing knowledge is inadequate due to lack of understanding of international Pharmaceutical marketing/pricing practices and market environment in various countries.

10. Inadequate manufacturing practices in comparison to those accepted in developed world such as change of API source, change of manufacturing locations, equipment, etc., with out proven stability/ bioequivalence may be creating inadequate technical work force for exports. The

national drug regulatory system though evolved substantially, has been in the need of strengthening its manpower and systems requirements.

11. Inadequate emphasis on Biosciences in education system leading to slower development in areas related to Biology giving away advantage to China.

3.4.3 Opportunities

1. India is faced with significant export opportunities , such as,
    i. US$40 billion worth of drugs in the U.S.A and US$25 billion worth of drugs in Europe are expected to go off patent soon. Assocham estimates that Indian manufacturers may capture 30 percent of that market. This translates to an opportunity of US$19.5bn which is significant considering the country's current exports of approx. US$7.25bn. However the figures need to be appropriately deflated since Indian opportunity will lie in generics equivalent of branded or patented drugs, which would be cheaper.
    ii. Generic launches by Indian manufacturers have increased in the United States from 93 in 2003 to 250 by 2008.
    iii. Compulsory licensing provisions negotiated in the Doha Round, allows for countries to import cheaper generic versions of patented drugs in the interests of public health. Thailand and South Africa have already started such initiatives from which Indian firms have benefited.

2. Due to the cost advantage in contract manufacturing & Research multi-national companies find it compelling to shift their production bases to countries offering such cost advantage. Typical of the industry which requires approval of manufacturing facilities by various drug regulatory agencies of the world involving a very high cost, once such business finds base in India it would continue with it for at least one & half to two decades.

3. Licensing deals with MNCs for NCEs (New Chemical Entities) and NDDS (New Drug Delivery Systems) offer new opportunities for Indian manufacturers.

4. Marketing alliances for MNC products in domestic and international market is another emerging opportunity.

5. Contract manufacturing arrangements with MNCs is estimated at 10% of patented markets estimated at US$450bn which is approx. US$45bn.

6. India has a very high potential for developing as a centre for international clinical trials due to its rich diversity.

7. India can become a niche player in global pharmaceutical R&D and possibilities exist for expansion of biotechnology generics (also known as bio-similars) and biopharmaceuticals.

8. There is a possibility of greater returns from an Indian entry into mature and more remunerative markets like Brazil, Japan, CIS, Russia, etc.

9. The Work Programme for the European Medicines Agency 2007 identifies greater co-operation with India - especially in the field of traditional and herbal medicines and remedies. Emerging preference for traditional medicines and herbs in the developed markets including lifestyle products and food supplements also presents an opportunity for the country in traditional medicinal systems & Herbal based products.

10. A rise in life expectancy generally, and increase in the population of the old, particularly in the developed world is causing higher expenditure from respective national health budgets compelling them to move to cheaper APIs and formulations which are India's forte.

11. Unleashing of a plethora of preferential trading arrangements, both bilateral and regional, offers opportunities for India to negotiate preferential access to partner markets for Indian pharmaceuticals in the long term and in a sustainable manner.

3.4.4 Threats

1. Product patent regime poses serious challenge to domestic industry unless it invests in research and development.

2. R&D efforts of Indian pharmaceutical companies are hampered by lack of enabling regulatory requirement.

3. Drug Price Control Order puts unrealistic ceilings on product prices and profitability.

4. Export effort is hampered by procedural hurdles in India as well as non-tariff barriers imposed abroad. For example:
    i. Indian manufacturers are prevented from bidding for government contracts as US permits bidders only from countries that are signatories to WTO Agreement on Government Procurement.
    ii. Indian manufacturers have to submit separate state level applications for marketing drugs in the United States as there is no nation-wide system of application even where FDA approval has been received.

5. Lowering of tariff protection has increased competition in domestic markets resulting in erosion of profitability.

6. Mergers and acquisitions by foreign companies particularly multinational corporations of a few Indian generic leaders may completely change the direction of India's pharmaceutical movement neutralising its thrust on generics and cost competitiveness.

7. The generics market in developed countries may be affected by a number of factors:
   i. The release of authorized generics by major drug manufacturers.
   ii. New mid sized players, establishing themselves in the generics market.
   iii. Increased competition due to newer Chinese and East European manufacturers. (E.g. there has been massive state level investment by China in the biotechnology sector – though at present India still has the edge due to IP laws.)
   iv. TA's entered into by the United States of America with third countries (e.g. the Morocco-U.S.A FTA) may be harmful to Indian pharmaceutical exports because of provisions for increases in patent terms, etc. The United States enters into a number of FTA's with different countries and while the exact text of these agreements differ from country to country, each of these agreements contains provisions which can be damaging to Indian exporters of pharmaceuticals partly also because of their provisions on patents. These FTA's contain a large number of provisions which increase patent terms for pharmaceuticals by allowing for patentability of new uses of discovered inventions and by increasing patent terms by taking into account the time taken to process claims (evergreening). These provisions go beyond TRIPS and hence it may not be possible to challenge these under the WTO Dispute Resolution process. However, the compatibility of these provisions with Article XXIV of the GATT needs to be examined.

8. Specific non-tariff and para-tariff barriers being increasingly adopted by other countries such as long transaction time taken for registration of drugs, insistence on completing long process for registration when the drug may actually have gone through the most rigorous process of registration such as the USFDA; insistence on allowing imports of only those drugs which are registered in some developed countries, etc.

4. Pharmaceuticals Sector and Opportunity Ahead

In general, there are several reasons which justify focusing on pharmaceutical exports. The most important of these reasons is the size of the industry, the growth potential of this sector and the advantage India enjoys in pharmaceutical manufacturing and services. Indian pharmaceutical industry has evolved in the last 20 years to position itself to global envy. It has the capacities of addressing needs of countries at different levels on the development ladder. Comparisons are some time drawn between the information technology and information technology-enabled services, and pharmaceutical industry to prove that state intervention and support may not be necessary as private sector is capable of spearheading itself. There is no doubt about the capacity of Indian pharmaceutical sector in taking the big leap forward. However, it may be necessary to note that pharmaceuticals all over the world are heavily regulated products. Comparisons with information technology will be miss-founded for several reasons, primary among them are the fact that pharmaceuticals serve survival needs in all societies and traditionally the sector got its momentum from government policies which developed its inherent strength.

There is another reason to contend that pharmaceutical industry deserves a greater focus today. A 'brand India' has gradually evolved around Indian pharmaceutical sector with the emergence of new segments of the industry, such as contract manufacturing, contract research services, bio-pharmaceuticals and Indian systems of medicines. It is even more necessary that this branding is adequately strengthened. This would require investments in brand building. It is perceived that government needs to prepare an action plan for brand building around pharmaceutical sector. This will also help in creating several spin off benefits such as for dealing with the problem of counterfeit drugs. Government of India needs to more proactively nurture this sector by addressing the missing links and strengthening the policy environment to encourage industry to find its rightful place sooner than later.

4.1 The Goal of Sector - Built on Track Record & Comparative Advantage

India can achieve significant revenue streams from exports by becoming a global centre for Pharmaceutical Generics, APIs and Innovative Formulations, an emerging New Chemical Entities (NCE) hub, service management centre for Multinational Pharmaceutical Companies (MPCs) such as, contract research/ custom synthesis, clinical trials, bioequivalence studies, biological studies, data management, etc. (refer Appendix V on comparative advantage of Indian pharmaceutical exports).

The main opportunities for the Indian pharmaceutical industry are in the areas of:

- Generics/ Bio pharmaceutical generics
- Contract manufacturing services for MPCs
- Contract R&D services like custom synthesis, clinical trials, clinical data management, bioequivalence testing, Stability testing, chemistry and biology services,

4.2 Generic Pharmaceuticals

The domain of generic pharmaceuticals includes pharmaceutical/biopharmaceutical intermediates, Active Pharmaceutical Ingredients and Finished dosage formulations. India's capabilities in various market segments have been presented (in bold letters) in Exhibit 1 below:

EXHIBIT 1: INDIAN CAPABILTIES IN DIFFERENT SEGMENTS OF PHARMACEUTICALS INDUSTRY

Geographical Segment

US generic market	EU market
Japan generic market	Latin America
Australian market	Africa and ROW

Generic Product Segment

Tabs and caps	Injectables and infusion
Ointments & creams	Oral solutions

Business lines Segment

CRAMS of API/formulations	**API manufacture**
Cuts synthesis / chemistry work in drug discovery	Formulation manufacture
Clinical trials/ data mgt etc, in drug discovery & development	NDDS/ Specialty generics development

Customer

MNCs of USA	MNCs of Europe
Generic Cos. /USA	Generic Cos. of Europe
Pharmacies / distributors	Other markets regulated

Therapeutic Segment

CVS, CNS	Antibiotics
Oncology	Derma/opthal
Steroids and Hormones	Controlled and subs

4.2.1 Generics Opportunity

A number of leading drugs go off patent every year and the generic pharmaceuticals penetration is increasing in all the countries of the world further raising the opportunity for exports in this segment. Approximately US$123 billion of generic products are at risk of loosing patents by 2012 (refer table 19, 20 & Chart 18). Even at a conservative estimate of 15% opportunity this translates into US$18.4 billion opportunity for India.

Table 19: Penetration of Generics Markets in Europe (2008E)

Country	Pharmaceutical Market Size	Generics Market Size (US$ man)	Generics Penetration (%)	Generics CAGR (%)(2004A-2008E)
Germany	34,913	13,451	38.5	15.6
UK	24,829	9,963	40.1	18.3
France	35,011	6,993	19.8	28.8
Italy	23,141	5,972	25.8	31.9
Spain	15,200	1,254	8.3	15.1
Netherlands	4,717	2,423	51.4	28.1
Belgium	5,406	380	7.0	16.5

Source: Wall Street Research, IMS, Datamonitor and Deutsche Bank

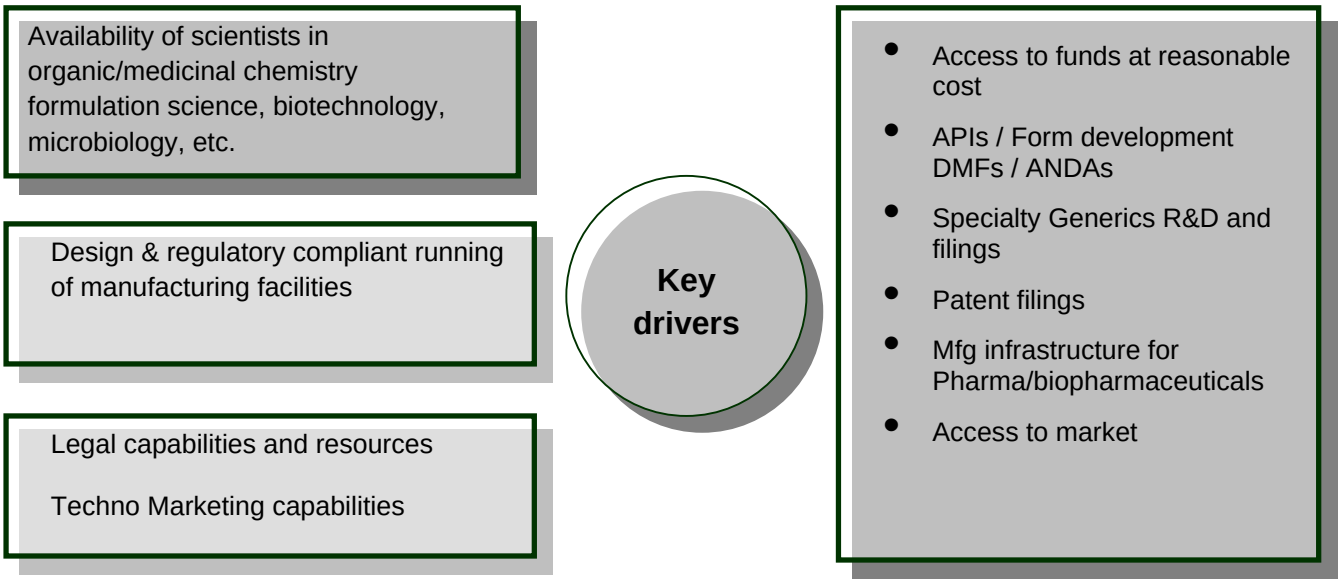
Table 20: Value of Products at Risk (figs. in US$ bn.)

Year	Value of Products at Risk
2002	17
2003	10
2004	16
2005	14
2006	19
2007	20
2008	20
2009	20
2010	28
2011	28

Source: IMS Health Market Prognosis Sep. 2007

The key drivers for growth of Indian generic pharmaceutical industry are presented in Exhibit 2.

Exhibit 2: Key Drivers for Promoting Indian Generic Pharmaceutical Industry



4.2.2 Opportunity in Developing Economies

A number of countries pursue self reliant policies and create non tariff barriers. In the new era of stricter regulation & enhanced understanding of drug quality, countries are learning the importance of economies of scale, strengthening of R&D and manufacturing. Lately, the structure of the industry has become capital intensive with stringent requirements to set up dedicated manufacturing and R&D facilities for different varieties of drugs to ensure drug safety and quality. Further, importing is far cheaper than revamping manufacturing for several product classes in countries with small populace and/or under developed industry. As the infrastructure is technology and human skill intensive, the cost of setting up and running such facilities to serve small populations has become uneconomical.

Further, the Declaration on the TRIPS Agreement and Public Health, at the 4th Ministerial Conference in Doha on the 14th of November, 2001 which the WTO adopted, has serious implications for world trade in pharmaceuticals and offers Indian companies specific export opportunities. Art. 31 of the TRIPS, which originally put in place the provisions regarding compulsory licensing, is understood as per paragraph 5b of the Doha WTO Ministerial Declaration on TRIPS and Public Health. This provides that "each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted." Usually these conditions are those of national emergencies and health crises when

nations are permitted to grant compulsory licenses on patented compounds to generic manufacturers who will produce the drug at low cost.[5]

This is important in the context of pharmaceutical exports because, as shown by the examples of Thailand[6] and South Africa[7], there are situations when patented pharmaceuticals become too expensive for developing countries and consequently, they import cheaper copies of these drugs. Indian companies such as *Cipla* and *Aurobindo* have been at the forefront of exporting drugs in these situations. This is specifically because there are very few countries, which have the manufacturing capacity to cater to situations. AIDS, etc are national emergencies and since India is one of the countries which has significant manufacturing capacity as well as a past record of providing for such situations, an important opportunity as well as social responsibility emerges for Indian companies[8].

Public health commitments of developing countries are increasing manifold in order to provide better health coverage to populations due to rising expectations and improved living standards. National commitments are also manifested in governments resolving to fight disease and malnourishment to improve productivity and mitigate poverty; and take up the challenges posed by occurrence in epidemic proportions of diseases such as AIDS, tuberculosis, malaria and many others. As populations in developing countries improve their living standards and get into the mainstream of economically productive modern living, emerging 'epidemics' such as diabetes and cardiac diseases, place new challenges before these countries, opportunities unfold for India in providing inexpensive but quality medicines to these developing countries.

As business in developed markets despite higher entry costs offers better returns today, most exporters are tempted to export to developed markets, at times, neglecting the less developed markets. Regulatory processes in such markets are also not adequately evolved thereby discouraging many exporters. However, there is a need to look at these markets with a renewed interest particularly because they are bound to evolve over time and today's entry investment may prove to be a seed investment offering better returns over time, secondly an entry at a later date may simply not leave any space for Indian drugs as the first mover's advantage might elude us, thirdly pharmaceutical exports may be a good strategic investment in these areas as it creates foundations for long term strategic relationships.

4.2.3 Opportunity in Developed Economies

US, Europe and Japan are the most significant economies in global pharmaceutical market. Developed markets such as USA, Top 5 EU countries and Japan are estimated at US$295-305bn, US$135-145bn,

[5] Art. 5(c), Doha Declaration.
[6] The Economist, "A Gathering Storm", June 7th, 2007. This mentions initiatives by Malaysia and Brazil to pursue compulsory licensing.
[7] The Economist, "The Price of Africa's Cheap Drugs", April 19th, 2001.
[8] Duncan Matthews, "WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem?", 7 J. Int'l. Econ. L. 73, (2004).

and US$64-68bn respectively with single digit growth rates (refer chart 23 & Table 4). The generics opportunity with in this market is relevant for India. Around ten percent of this market estimated between US$49.4 – 51.8 billion can be taken as the size of the opportunity for Indian generics.

Generics need not be promoted to doctors in many markets such as USA and assume character of a commodity in these countries. The cost of promoting to doctors and setting up drug promotion structures would other wise be very high for Indian firms and the only entry cost in generics markets in these countries is limited to the cost of developing a DMF (Drug Master File) or ANDA (Abbreviated New Drug Applications) and the filing costs. In view of this, many developed economies are important target opportunities for pharmaceutical generic manufacturers.

Emerging markets (Brazil, China, India, Mexico, Russia, South Korea and Turkey) are estimated at US$85-90bn. (12-13%) and rest of the world is estimated at US$125-135bn growing at 7-8 percent in the coming years. Emerging markets have significant generic component due to historic reasons of patents applicability.

4.2.4 Bio-generics Opportunity

Bio-generics are nothing but generic versions of biological products. With around 200 companies, India's biotechnology sector is growing fast and is in the early stages of development with initial emphasis on vaccines and bio-services. The break-up of Indian domestic biotechnology market is given in chart 19. This industry grew by 37 percent in the year 2006-07. Total biotechnology exports stood at US$763 million during 2006-07 with 75 percent of it coming from biopharmaceuticals.

IMS estimates that biotechnology products accounted for over 10 percent of global pharmaceutical sales, 20 Patents on the first generation of blockbuster biopharmaceuticals are beginning to expire. Sales of bio-generics are flourishing in the unregulated markets. The only regulated-market approvals so far are in Australia, granted in October 2004 for the recombinant DNA growth hormone Omnitrope, manufactured by Sandoz, as well as in the EU, granted in April 2006.

Table 21: India's Domestic Bio-Technology Market Segmentation (2006-07) (figs. in US$ mn. & %)	
Bio-pharmaceuticals	76
Bio-agriculture	8.4
Bio-services	7.7
Industrial Products	5.5
Bio-informatics	2.5
Source: Pharmexcil	

Firms based in India and China could be among the successful firms to bring bio-generics to the regulated markets very soon. The first bio-generic product was approved by the European Medicines Agency (EMEA) in April 2006. Experts believe that the patent expiry on over 6 major drugs in near future can generate over two billion dollars revenue (Datamonitor) for India.

Biological products are different from chemical drugs in terms of size, manufacturing process and clinical safety. They are much larger and more complex than small molecule drugs. These products are made from live cells and it takes months to produce a run or a batch. Precise manufacturing control is necessary to obtain consistent results. Drugs regulations are traditionally geared towards small molecules which may not be relevant to biologics. Issues of safety and efficacy are even more critical in case of biologics. The regulatory pathway for biologics needs to take these specificities into account. While generic drug approval pathway is premised on ability to make and show that generic drug is the same innovator drug, biologics from different manufactures will be similar (bio-similars) not the same hence different regulatory pathway with different scientific standards is required.

India is already at an advanced stage in infrastructure development to compete globally with significant advantage of low cost of innovation, low capital requirements and lower costs in running facilities. Owing to a large population, well established manufacturing processes, R&D infrastructure, India is strategically well positioned to take care of import needs of several nations. India has huge comparative advantage as compared to the west & the Rest of the World in this domain and as non tariff barriers breakdown due to economic pressures, India can emerge as a global manufacturing hub.

On the other hand, the European generics market, CIS, Japan and most parts of the world hold substantial promise. Also the opportunities have further increased due to the fact that Indian companies have acquired around US$2 billion worth of pharmaceutical companies overseas in the recent past.

5. Accelerating the Growth of Generic Pharmaceutical Industry

5.1 Paucity of Funds to Move to the Next Orbit

Most organisations in India, China and developing countries have begun their journey recently. Establishing a regulatory compliant manufacturing infrastructure and developing a quick product portfolio to run these manufacturing engines is quite expensive and consumes most of the borrowing power. The availability of funds for long gestation but high return projects, building broad product / market portfolio, entering into new technologies, etc., is an important issue which deserves attention of the government.

5.2 Complex Technologies

India's presence in injectible dosage forms, steroids/hormones, sustained or controlled release drugs, poor solubility drugs with difficult bioequivalence, dermatologicals, ophthalmologicals, etc., is almost negligible. India has a number of DMFs and ANDAs in conventional vanilla generic products either for off patented products or patented products. Typically, an immediate release generic ANDA could cost around US$1million to develop and register. A specialty generic such as sustained release formulation could cost more than US$3-4mn. Neither small companies nor public companies with huge pressure from stock markets can build large or specialty portfolio in the current circumstances.

Many of the untapped opportunities are not impossible to capture as several corporations like Impax, Schwarz Pharmaceutical, Abrika, Skye Pharmaceutical and scores of companies have hugely benefited from the focus on specialty generic APIs and formulations. With stretched balance sheets a new initiative has to be conceived to push the industry into the next orbit. India with significant lower costs of innovation and testing is better placed to capture these opportunities.

5.3 Creating Broad Portfolio

It is a known fact that broad portfolios are crucial for success. Broad portfolios come either through mergers or through significant manufacturing and R&D investments. The product portfolios of most Indian companies are insignificant in size as compared to competitors. The R&D costs, being revenue expenditure, by and large in generics, to create such a product portfolio further stretches the profitability and market capitalisation of the companies. Novel financing concepts to fund intangible assets are practically non existent.

5.4 Building Market Portfolio

Commercialisation of intellectual property across several markets enables enough profitability in the current competitive context. Most Indian companies are not having financial muscle to file drug registration applications in all target countries. Unlike India, the drug registration costs in Europe,

Australia, Canada, etc., are prohibitively expensive (the registration costs are at least 50 to 200 times more than Indian costs) leave alone other costs such as meeting their country requirements like bioequivalence with local reference product, etc. Once again neither alliances exist between local players to penetrate several countries nor are venture capital concepts prevalent to push innovation to several markets. (Refer Appendix VI for Mergers & Acquisitions scenario of India.)

Building Portfolio for Untapped Highly Attractive Opportunities

Prioritised funding by institutions like EXIM Bank through Special Purpose Vehicles (SPVs) has to be pursued aggressively. Such SPVs shall contract product development work for excellent but high initial cost opportunities such as specialty generics, topicals, steroids, hormones, biopharmaceuticals, non infringing process based DMFs/formulations, ANDAs, etc. Obviously, such funding is not a loan stretching the balance sheets of companies nor an equity dilution in the current company. An agreed percentage of revenues from the SPV funded projects will go back to the funding bank towards the investment and Internal Rate of Return (IRR). Once the funding BANK recovers its investment and IRR, the ownership of the products will flow back to the company without complications. Public and private initiative on a mega scale in this area is essential for jumpstarting India's pharmaceutical industry into a higher orbit achieving quantum growth.

5.5 Access to International Markets- Need for a Policy Environment

Inter & intra country competition is significant to capture the opportunity in pharmaceutical intermediates, APIs and formulations. The intermediate, API and generic formulators from India, China and established European API/formulator firms are facing three challenges:

a. Growing consolidation of large generic marketing organisations
b. Consolidation of pharmacies termed as pharmacy chains and distributors and
c. High cost of developing ANDAs/DMFs and subsequent registration at key markets.

Hence, the number of players sourcing APIs or formulations is coming down giving way to tremendous bargaining power in the hands of large generic firms or distributors/pharmacy chains, obviously causing price erosion and pressures on profitability. The financial power and business wisdom in developed world ensured significant consolidation in the generic marketing organisations and distribution/pharmacy chains fronts.

At the same time new players like India and China had very little consolidation or mergers between the native firms causing heavy crowding of markets and price erosions. Consolidation between native companies could create large corporations who in turn either can with stand the pressure of consolidated

buyers or buy access through purchase of relevant marketing/distribution organisations. The costs saved in duplicated research efforts and the avoidance of capital expenditures can boost the financial muscle while at the same enabling them to compete with the global generic conglomerates. However, as at present, fragmentation is the order of the day in developing countries. Institutional approaches for encouraging consolidation need to be examined. A consortia approach to creation of a special purpose vehicle adequately supported by venture funds, exclusively charged with accessing developed markets could be considered as a means of breaking market monopolies in these countries.

Developed country players are using these opportunities to vertically integrate through acquisitions and there by compete with the emerging third world players. As the opportunity to become "big" comes down, the opportunity to be self reliant through native companies' drug discovery programmes extinguishes, exposing large population economies such as India to western inventions only. The per capita income differential being very high, the affordability of international drugs can become a significant issue. Limited resources of fragmented companies do not allow M & A activity to buy access into other countries. In several countries, governments have initiated, through policy action, strategic Mergers & Acquisitions in national interests.

Engineer Alliances to Protect Strategic Interests of the Country

Alliance initiatives between domestic companies funded through a venture capital concept by Exim bank, etc., should be promoted. Prioritizing funds to promote internal M&A is necessary in creating large Indian companies to counter the increased bargaining power of consolidated buyers.

The recent takeover of controlling interest in Pharmaceutical major Ranbaxy by the Japanese multi-national Daiichi has raised several questions. India has witnessed in the last five years several takeovers by Indian companies of brands, equity holdings, controlling interests, intellectual properties etc., all over the world. These efforts have been consequences of realization that economies of scales have to be achieved, difficult markets have to be accessed, monopolies of multi-nationals in holding patents have to be breached and strong research and development initiatives have to be taken. Companies like Ranbaxy, Dr. Reddy, CIPLA and others have for a long time been at the vanguard of this 'movement' and represented the new belligerence of the Indian pharmaceutical industry.

Ranbaxy takeover appears to be a 'perfect fit' at the firm level. Ranbaxy needed huge doses of capital, to meet high costs of patent challenges, R&D and high entry costs in foreign markets; Daiichi on the other hand required large network of markets and proven capacities and know-how both in research and manufacturing. Over 11% of the global pharmaceutical demand is generated in Japan. The national health commitments in Japan due to a variety of reasons including the rise of old age population is

causing Japan to look at generics to reduce their national health spending. Therefore, it fits well with the perspective of a Japanese multi-national to acquire a company like Ranbaxy. Some other companies at the top end of Indian pharmaceutical industry have also been vulnerable, lately.

However, these developments need to be seen in a perspective which is not constrained by market dynamics alone. Indian generics are addressing typical concerns of developing countries in their larger national health commitments. The generic requirements of developed countries are somewhat different from those of developing countries for a variety of reasons. Indian generics operate at very low margins which make them quite competitive.

Some contemplate that a multi-national innovator like Daiichi may not look at Ranbaxy acquisition in the same perspective as we do. They apprehend that over time Daiichi might like to re-orient Ranbaxy to serve the needs of its Japanese generics market. Secondly, in order to take advantage of better realization from developed markets, Ranbaxy might re-orient its production basket more specific to the developed country needs. Thirdly, Daiichi may use Ranbaxy's excellent R&D infrastructure to developed country requirements rather than the larger public health based developing country requirements. Fourthly, Ranbaxy's passing over to an innovator parent, may dampen the 'spirit' of Indian pharmaceutical industry.

This may increase the vulnerability of Indian companies. It is noteworthy that most of the big Indian companies are small by global standards. It may be worth recalling that controlling interest in Ranbaxy could pass on to Daiichi in a deal worth US $ 4.6 billion. There may be several other companies in the same league where controlling interest may require much lesser investment. In such cases a take-over would be even easier. It is apprehended that a few more takeovers of this kind may neutralize the sting out of India's generics revolution. This may even be a good strategy for the 'innovators' to 'silence' the generics frontrunners, thereby retaining their innovation foundations while acquiring huge generic potential.

It is no surprise that hurdles have been coming in the way particularly accentuated in the last five years. Whether it was the debate on ever greening and data protection; patent challenges in the US; a variety of subterfuges on 'counterfeiting', including the debate in WHO general assembly or the regulatory biases reflected in some markets in Africa or other developed countries or hasty efforts at developing a multilateral regime, which have been confronted with a sustained and consistent approach adopted by the government and the domestic industry. Government of India has withstood these challenges with determination. But it is time to consolidate the progress in comprehensive manner.

Companies, even in the top league in India have been finding the going tough due to difficult and complex access regimes in developed markets such as US and Europe; and limited financial, technical and human resources at their command. Even if India is able to take a 10% slice in the emerging market in developed countries it will open an opportunity of around $50bn. at current prices of patented and branded drugs. In terms of generics it will be much lesser yet huge in proportion to our present exposure. In order to catapult this sector into the next orbit of growth, strategic investments in research and development, technology and market penetration are necessary.

Access to developed markets cost a fortune in terms of product dossier development expenses, regulatory filing costs and potential litigation costs. It is estimated that preparation and registration of a Drug Master File or an Abbreviated New Drug Application (ANDA) cost (product dossier development cost) between $ 1 million to $ 5 million in the US. Similar expenses are incurred in other developed markets. Developing a non infringing process to come around the IP bottle necks is another huge expense. Breaking the complex maze of IP woven by multinationals requires deep understanding of law and practice and it costs large doses of money. Most developed markets are now under tight grip of a few distribution entities across the world. Even the larger Indian companies have found it difficult to meet these costs as great risks are associated with them.

A very liberal domestic entry regime and a fragmented structure of industry make India vulnerable and it is therefore suggested the country needs consolidation of domestic industry.

All of this throws up challenges of unique financing mechanisms and institutional forms besides investments in creating capacities in research, law and science and technology.

Indian pharmaceutical industry has reached its enviable position with no less contribution from an encouraging domestic policy and legal environment. The sector has been nurtured through government policies and a strong human resource base particularly in chemical sciences, supported lately by contributions from bio-technology. Huge opportunities are awaiting Indian pharmaceuticals in potential space to be created by drugs going off patent, contract research services and manufacturing, etc. The industry does not need hand holding but would need in place, strategic controls and directions in national interest and for exploring global opportunities. Therefore, it may be questionable to believe that pharmaceutical sector in India does not require adequate props from the establishment. One takeover may not shake the confidence of the industry; however a few of them could have potential to do so and might change the entire course of pharmaceutical movement in India. Some might suspect the need of regulatory additions in the modern market-driven environment, but it may be opportune time to reflect if we need greater policy intervention to help pharmaceutical industry catapult to the next orbit.

5.6 Promoting Internationally Competitive Manufacturing

Currently, there are considerable efforts in various countries for developing pharmaceutical exports. There are countries which have specialised in contract manufacturing for global markets. Pharmaceutical industry for international generic markets is capital intensive as several varieties of products need dedicated high cost facilities. Profitability can be achieved only when the product penetrates various markets across the world. Further, different countries have different packaging specifications.

1. Transfer pricing to EOUs or SEZs is another issue which needs consideration. The Indian entrepreneurs have invested in huge capacities in the recent past. Appropriate capacity utilization in multi-product facilities takes a long period of time. Under the current excise rules, the transfer price from one unit of the company to other unit is well defined. However, in the initial phases of development, the transfer price from a new unit could be far more than the available market price or export price to outside customers. In such cases the tax benefit offered by SEZ or EOU suffers. Hence for inter unit transfers, for the purpose of exports, either the transfer price as calculated by department or price sold to the market (as was under earlier law) should be considered. Although the anomaly looks trivial, it has serious consequences as it will have impact on make or buy decisions affecting the domestic growth.

Streamlining Inter-unit Transfer Pricing for Export Purpose

Pharmaceutical manufacturers should be given the option for determination of transfer prices for internal movement of goods based on cost price as calculated or price charged to external customers.

The list of key cities where inter-unit transfers are smoothened by excise department needs to be expanded realistically.

2. Recently some inputs such as steel are attracting export duty. As per the recent law, SEZ s when they buy steel, should pay export duty. Pharmaceutical facilities consume lot of steel and such duties increase the capital expenditure of the unit as compared to domestic unit. While the intention of every SEZ is to capture exports, there is often a need to sell certain portion in domestic and capital cost differentials due to such export duties suffered by units in SEZs will work against the interests of the policy.

Exemption from Export Duties to SEZ Units

Export duties applicable to exports should not be charged to SEZ purchases.

3. Pharmaceutical establishments take considerable time for designing, constructing with advanced air handling systems and containments, validation of each and every equipment, facility, taking test batches, consequent documentation, testing of bioequivalence, waiting for inspections and consequent product approvals. This is quite a slow process often taking more than 48 months to achieve meaningful commercialization. Considering the nature of the industry, the law should provide additional time for commercialization of facility and availing of tax benefits. In addition, a fixed percentage of capacity should be allowed to be sold in domestic market instead of fixed percentage of annual sales to allow the units to gain experience and recover overheads. In a knowledge intensive industry, it is very difficult to retain people during the period of testing and waiting for various approvals. Allowing production for domestic market firstly ensures good quality drugs being available for domestic market and secondly, it helps the work force and managers to have sufficient experience for successful inspections and approvals. Consequently the year of commencement of tax benefit should be computed from the year of profits. The nature of the industry is time consuming and hence such an exception is rational.

Formulating Practical Norms for Pharmaceutical SEZs

Domestic sales up to a fixed percentage of capacity installed should be allowed for export oriented pharmaceutical units.

First year of profits should be considered for beginning the tax holiday period.

5.7 Promoting Competitive R&D

4. R&D conducted in house enjoys weighted deduction as an incentive. However, there are a few ambiguities in the definition of R&D itself in the context of pharmaceuticals R&D. For example, when a R&D unit develops a formulation, it has to be tested for bioequivalence. Such a bioequivalence testing gets out sourced. Similarly, an R&D may develop a production process. Such process has to be scaled up in commercial facilities and often some rework is needed. Such production batches in scale up have to be outsourced in commercial facilities, as R&D in general may not have large manufacturing facilities for scale up and process refinements. Outsourcing of scale-up operations cannot be performed at universities, etc. Such outsourcing costs in pharmaceutical R&D are common and should be allowed for weighted deduction.

Treatment of R&D Expenditure for Tax Purposes

Outsourcing done by approved R&D, for example bio-equivalence studies which are integral part of R&D should be considered for weighted deduction.

5. The law to develop commercial R&D firms is very restrictive. It is stipulated that these should be independent companies managed by significant number of outside directors having significant sales to third parties. Setting up large bioequivalence centers, or large contract research firms, etc., are extremely capital intensive. Such centers have long pay-back period and will dilute the Return on Capital Employed (ROCE) of many companies. In this context, the incentive to build such contract research centers by large companies wanes. Only upon the guarantee of promoting companies they will be able to raise funds enough to meet the capital intensive nature of the segment. It is therefore necessary to give tax incentives to such subsidiaries for engaging in commercial R&D. The external component targets should be liberal as it takes considerable time to shift contract research from developed economies to India. For example a firm doing bioequivalence testing should keep records for several years to enable the auditors of government agencies to inspect and audit. Failure in inspections means the product withdrawal or non approval. As pharmaceutical business is extremely regulated, lot of effort goes into establishing credibility and then acquiring business. The outsourcing decisions of corporates consider such things as financial stability of testing centers in addition to the competence. Considering the exceptional nature of industry, the rules should enable large corporates to set up divisions for commercial R&D availing tax deductions or holidays.

Permitting Commercial R&D Subsidiaries for Tax Exemption

Commercial R&D firms promoted by established firms as subsidiaries should be allowed for the purpose of tax holidays in pharmaceutical industry.

5.8 Overcoming Cost Escalation in Human Resource

Skill set is strong only in limited number of organisations pushing up the costs of innovation and manufacturing. India traditionally enjoyed the benefits of low costs coupled with committed skills. Costs are rapidly increasing in the relevant manpower base such as scientists, regulatory affairs personnel, manufacturing personnel, pharmaceutical lawyers and international business development personnel.

Availability of right talent at meaningful costs should remain India's strength for some more years and it is feasible to achieve this if some initiatives are taken now. There are no formal and significant efforts to diffuse innovation capabilities due to lack of linkages between academia, public institutions and industry. It is generally not in the interest of the country for select players only to continue to enjoy the competence of a large skilled pool of human resource. The industrial growth and continuity is dependent on the creation of large skilled population. Intense public initiatives have to be conceived and implemented in this area.

In most parts of the world relevant innovations take place at all three key centres such as universities, public institutions and industry. In India, beyond initial beginnings given by public sector and public

institutions, the linkages were not established sufficiently between these three centres of innovation. There is a strong case for developing several centres of excellence in leading universities and scientific and technical institutions dedicated to specialised sub-sectors of the pharmaceutical sector and focussed on advanced research and dissemination. A Research and Development Fund of Rs. 150 crores alone may not be adequate enough to deal with challenges mentioned above. A strong public-private initiative involving institutions at all levels is of immediate relevance.

Exports and globalisation capability is enjoyed by a few large players in India. Competency in APIs/ formulations, intellectual property creation, facility design and maintenance, knowledge of global regulatory affairs, legal acumen, and expertise in managing international executives and understanding of global markets is not available beyond a few players.

In the pharmaceutical industry, the government machinery dealing with bioequivalence, site inspections, GMPs, etc., is often a big resource to the industry. One can often see scores of consultants or managers who were earlier on the rolls of Food & Drug Authorities contributing to the development of the private sector. Foreign site inspections to approve imports by government agencies are a means of gathering immense knowledge in various countries. India by and large does not capture this benefit as the Indian regulatory bodies are not focussed on international site inspections of APIs or formulators to evaluate cGMP and the data submissions.

The work force in India beyond the internationally approved plants reportedly, has a different set of experience in manufacturing processes. The present drug regulatory regime does not mandate bio equivalence at the time of registration of a new drug. The Indian drug registration process is not only less expensive but is also less demanding. The need for bio equivalence does not merely increase the demands over the applicant but also helps in qualitative improvement of drugs, creation of superior infrastructure, better skilled manpower and encourages investments in these areas. It has a multiplier effect on the entire drug production and regulation process. The drug registration regulatory regime, therefore, in India can adopt bio equivalence as an important criterion of new drug registration. As there is no mandatory bioequivalence testing (apart from a few exceptions) or research to prove equivalence in case of changes in processes or sites or machineries in production, the attitude in manufacturing may become lax and counter productive, sometimes even in internationally oriented Indian facilities. Hence though thousands of firms exist, there is shortage of relevant skill set raising the costs. If the need to align with international norms becomes mandatory, the industry will produce large number of skilled people in manufacturing, regulatory affairs and R&D at least in the medium term beating the wage cost escalation.

Enhancing Pool of Trained Professionals

The country has to facilitate Learning and Development vigorously through public initiatives in enlarging the pool of skilled population in the areas of:

- **Law**
- **Regulatory affairs**
- **Knowledge of market environment at the global level**
- **Patent procedures & filing**
- **Non Infringing Processes -concepts & strategies**

Pharmexcil should facilitate L&D for pharmaceutical professionals to enhance the learning opportunity and available pool of talent.

Treatment of Investments in Quality on Par with R&D to Enhance Quality and Skilled Scientific Personnel

Insisting on stringent cGMP (current GMP) and bioequivalent drugs for key drugs can turn the table in enhancing the skilled population. Only when organizations have a need for higher quality, employees in such organizations will have incentive to learn, update and join the elite trained pool of scientific personnel. While it directly benefits in increasing the skilled population, it also benefits in assuring quality drugs to Indian population. This is also a progressive step in controlling spurious drugs. Considering investments for Quality Control equipment at par with R&D capital goods purchases is a crucial step in rejuvenating Indian quality environment.

5.9 Reducing Dependence on China in Intermediates

Indian pharmaceutical sector has been sourcing its requirements of chemical intermediates and bulk drugs in large quantities from China over sometime. This has been necessitated due to cost competitive supplies from China acquired by them *inter-alia*, due to economies of scales and diversity of portfolio. A situation has come when almost 60 to 70% of our requirement of intermediates is sourced from China. Recently China cracked down on its chemical industry in order to enforce environmental legislation leading to short supply of chemical intermediates, increasing their prices uneconomically for Indian drug manufacturers. On one hand, this severely affected bottom lines of Indian companies while on the other their supply schedules were also disturbed.

India must reduce its dependency for these intermediates on China. This would be possible if we identify other alternative markets in our vicinity which can be equally competitive if their scales could be increased. Alternatively, there is a strong need to review domestic capacities for supply of drug intermediates so that Indian drug industry is not over dependant on one country. It may be appropriate to examine production capacities in neighbouring countries to suit our industry requirements. India must

create a policy environment for its small and medium chemical industry to position itself appropriately to address back-end needs of the pharmaceutical industry.

Reviving Indian Drug Intermediate Industry

The energy and labour costs differential has virtually eroded. In the past intermediate industry migrated to China due to these reasons. India is emerging as a significant supplier of finished APIs and formulations to regulated markets and ROW. China can capture our market with the strength in intermediates if India does not pay attention to building intermediate industry. Every year, several new chemical entities loose patent protection and the corresponding opportunity for several intermediates and finished APIs emerges. An expert panel needs to study the potential intermediates that can come back to Indian manufacturing arena. Genuine foreign site inspections, analysis of imported samples of every consignment, in-depth review of regulatory submissions will put Indian industry on par with imports at least in strategic intermediates.

5.10 Hurdles in Tapping Narcotics based APIs and Formulations

Drugs like codeine, etc., classified as narcotics have a very significant presence in the global market. As per IMS Health, over US$9 billion opportunity exists in global narcotic pharmaceutical market. While certain countries have severe restrictions in the imports of scheduled drugs, there exists an opportunity for certain sub classes of narcotic drugs. While safety has to be kept in the mind always, the opportunity can not be ignored.

For contract manufacturing of pharmaceutical products requiring narcotics DMF material, the same has to be obtained from vendors approved by respective drug regulatory authorities of importers' country who (vendors) are often situated abroad. To cater to this segment, Indian manufacturers will have to necessarily import from these vendors and export the finished pharmaceutical product to the foreign buyer. Indian manufacturers requiring narcotic DMF have to apply for annual quota for importation to DCGI, New Delhi. The application has to be made in the month of April, one year in advance and quotas are granted in the month of March of subsequent year.

Currently, the procedure for imports of narcotics is cumbersome creating avoidable hurdles to genuine manufacturers resulting in abandoning of this opportunity. Imports of narcotics material is permitted only through Government Opium & Alkaloids Works (GOAW) which is the canalizing agency established in this regard.

The manufacturers have to apply to Government Opium & Alkaloids Works (GOAW), Delhi for importing the same by them. The importer has to deposit the entire purchase cost with GOAW in advance. GOAW

in turn would seek approvals from Ministry of Finance involving approvals from Internal Finance Unit (IFU), expenditure department and revenue department. The approvals require passing through several layers of hierarchy including submission to finance minister before it is finally returned with approval to GOAW. The entire process will be repeated from stage-1 if the application is returned to GOAW due to any query raised at finance ministry.

NOC & import permit is also mandatory from Narcotics Department, Gwalior. After receiving such permits, GOAW issues purchase order to the manufacturer based on which the manufacturer can place order on foreign vendor. Usually foreign vendors also require additional time to obtain necessary permissions and export licenses to supply narcotic DMF material. The narcotic material thus imported will have to again travel to GOAW by road from port of importation for quality control clearance by them before it is finally released to the domestic manufacturer.

The production at the manufacturers' premises is also strictly regulated requiring manufacturer to account for every single gram leaving no room for errors. Production records have to be maintained and narcotic materials are required to be stored in cages and vaults as per specifications under the law in this regard.

The entire process imposes the challenge of risk on the manufacturers and is fraught with huge delays and consequent financial costs. GOAW imposes service charges besides duties and CST to the tune of 20%. A further 8 to 10% cost escalation occurs due to financial cost for the period required for obtaining the approvals which is reported to be between 7 to 8 months. In addition to this inventory carrying and handling costs of 8-10% on the stocks maintained under quota system has to be borne rendering Indian manufacturer uncompetitive in the international market.

India, therefore, loses export opportunity of this sector. Moreover, due to the stringent regulation & control of narcotic materials, the domestic manufactures are unable to undertake product development for international markets. The opportunity is thus killed in its nascent stage itself. This is evident from the fact that India thus far has not filed a single DMF for narcotic substance with US FDA or any other drug regulatory authorities abroad and has thus barely penetrated this market.

It is therefore, necessary for clear, simplified time bound guidelines for importing narcotic materials for drug development and contract manufacturing when DMF materials can not be offered by narcotics board. The concerns against the use of narcotics and their illegal trade are very genuine and must be respected. However, within premise of this broad understanding, there is need to examine the present procedure under the concerned legislation to make narcotics based drug manufacturing relatively simpler and growth generating.

Many firms are averse to participate in this opportunity due to very difficult conditions and delays in adhering to current procedures and controls. For example, contract development services will need import of DMF approved narcotics. Such dossiers or technologies may be licensed to markets for production at foreign sites. There is an advantage for India in this sector as the country produces significant quantities of narcotic raw materials and this competitive advantage can be better utilized by introducing some reforms in the present regulatory procedures..

Looking At Narcotics Formulations as an Important Opportunity and Not Just A Menace

In view of the above, it is therefore necessary, to simplify the procedure and to capture the global narcotics business in certain classes of narcotics. The entire process of approvals from multiple agencies such as DCGI, INCB, Ministry of Finance, State Narcotics Boards, the quota systems and canalization should be relooked at for promoting export production. The genuine manufacturer exporters may be permitted to directly import narcotic substances based on risk profiling and past records with minimal regulatory constraints.

The quota system should be done away for export production as it is difficult to assess import requirements one year ahead especially when the country desires to capture a bigger share.

Obtaining INCB permission for each consignment of the same material for same importer and by the same vendor for certain classes of narcotics is not present even in developed countries such as Europe where the regulation is very stringent and can be done away with.
Online submissions, approvals and clearances should be considered.

5.11 New Technologies

Biocatalysis, Organocatalysis, Nanotechnology, etc., are some of the new technologies that will have significant influence on the industry. Development of biocatalysts requires a significant interface and cross functional understanding between chemistry and biology. Developing micro organisms which act as enzyme catalysts accelerating certain chemical reactions which otherwise take multiple steps or cause lot of environmental issues is an essential technology.

Being one of the largest producers of APIs, the country needs to develop biocatalysts either to reduce load on environment as also to reduce cost of manufacturing. As most of the API production is being shifted to India and China, the incentive to develop this science with respect to APIs will be less in developed world. Europe, US and other key countries are focusing on biocatalysts for significant gains in food processing, environment management, etc. Companies working on biocatalysts like ‘Codexis’ have

succeeded significantly, licensing the technology/ biocatalysts with out incurring huge capital expenditures in setting up production units. Technologies based on biocatalysis helped European and US firms to cut several steps in chemical process and compete comfortably with low cost countries.

Typically, many API companies in India have insignificant understanding of biology and managing of micro organisms. The task should be evaluated and should be focussed as industry projects at premier institutes and universities.

In general, China is stronger in biology and rapidly improving its skills. API companies in China are similar to India except that China is a dominant force in fermentation technology. Potential opportunities if harnessed only by China in this area may mean loss of business in such APIs.

Large state investment has changed the landscape in China thwarting Indian attempts to succeed in bio-generics. Most of the biotech research in China is underwritten by the government (China participated in human genome project) enabling Chinese firms to produce hepatitis vaccines, recombinant insulin, interferon and other generic therapeutic biologics. Department of Biotechnology in India is working with industry and has contributed significantly in bringing out several vaccines for growth. Biotechnology has vast implications in agriculture, environment, pharmaceuticals, etc., and obviously overlap of projects takes place. The biotech industry in the world is characterised by small firms founded by former professors or scientists with funding from either venture capital or by government. Substantial growth in the knowledge of biology and chemistry is essential for success. The strong determination of government of China aggressively promoting the institutions in this sector and experts believe that China may overtake India significantly in spite of India's advantages of English speaking employees, regulatory and manufacturing competence, etc. The current strategy of developing projects and subsequently trying to market or commercialise them should be suitably amended. Instead identifying projects in a consultative mode with the industry in relation to global developments and opportunities may produce more useful results. Associating universities and technical institutions in research and development work and licensing of consequent benefits to domestic firms may be a sound strategy. While the Departments concerned have more or less similar approach a certain amount of industry interface and aggressive approach in a global setting is essential.

Focusing on Immediately Commercialisable technologies By Government Institutions

One or two Indian scientific institutions should work along with domestic firms to identify target products which can benefit from these new technologies and take up projects. A small percentage of costs should be shared by industry firms and the technology may be licensed by them with out bottlenecks.

Banks should provide capital for taking up commercialisable R&D

R&D being a revenue expenditure, certain new technologies are taking a back seat in corporates that are already struggling for profits. Competing countries are investing in new technologies like biocatalysts, etc. forging ahead of India. Banks should develop SPV concepts to fund these technologies.

5.12 Reviving Fermentation Products

India has lost large volumes of fermentation business such as Pen G, 7 ACA, etc. to China with its low costs in energy. China has gone for huge capacity expansion and captured global market with very aggressive pricing. It enjoys substantial profitability, after the global capacities were shut down. Power interruptions are fatal for fermentation industry. Fermentation skills are essential as several APIs come from fermentation industry. Several biotech products need fermentation. Although it is difficult to assure the quality of power, the capital required for back up power plants should be evaluated with a priority focus in fermentation industries. It is essential that the skills in this key segment should not be lost forever to competing nations.

Reviving Fermentation Capabilities of India

As the cost disadvantage is disappearing between China and India in energy and labour, the country should relook at fermentation R&D, Lyophilised pharmaceuticals, etc., Soft funding for fermentation projects as a kick off to bring back select intermediate industry especially in biopharmaceuticals and certain recent fermentation based intermediates/ APIs may be considered.

5.13 The Linkage with Educational System

a. A number of young students are moving away from pure sciences like chemistry, biology, etc. to other non-science disciplines as science education loses its attraction in the present socio-economic milieu. Premier institutions like IITs, NITs, etc., capture students for engineering and do not have adequate schemes to attract students in sciences especially after 10+2. Integrated courses in these institutions are considered only second option for aspiring engineers.

b. Most law students coming from good law schools have back ground of humanities and combination of life sciences with law are almost non existent. Lately some National Law institutions have adopted combined courses of science and law but they are very few in numbers and not yet very popular. A majority of law graduates in India are from arts disciplines and are finding difficulties in relating to the life sciences industry requirement. Legal understanding is a key component of international pharmaceutical business. Hence, India must develop law and life sciences connect urgently.

c. Educational institutions lack relevant exposure to industry due to almost non existent interface between academia and industry.

d. Similarly, there is a strong need for content oriented updates or programmes in regulatory affairs, IPR matters, legal issues, scientific developments, etc. for existing professionals. As the industry is nascent, the limited skilled manpower is becoming expensive and the pool is not enlarging as the efforts to enhance the pool through learning and development programmes are insignificant.

Attracting Talent to Chemistry and Biology

An integrated postgraduate course in chemistry could be offered in NITs, IITs, NIPER, and leading universities at the 10+2 level. Most bright students prefer engineering streams. Pure science in local colleges has become an unattractive destination. While chemistry is fancied to some extent, biology has much less attraction. Integrated courses in biology could be introduced at leading institutes focusing on microbiology, biotechnology and pharmacy. The quality of education in some of the private institutions offering these courses requires in-depth examination.

Integrated courses in law and life sciences should be introduced in premier law schools and universities.

A legal frame-work should be developed for tapping and developing the student potential while employing them for project works. However, as industry is not willing to offer projects in view of confidentiality issues, the legal framework should provide for confidentiality agreements by students and professors of universities. The confidentiality agreement should carry particulars such as passport details, permanent address of the student, etc. to trace them in the event of violations of such confidentiality agreements. Further, government should also make it mandatory for Universities Professors to produce a minimum number of projects/research works each year. Patentable research should be the drive at Institutions and universities. Increments and promotions may be linked to the research output and industrially commercialisable projects undertaken by their students/ departments. Grants etc could be linked to the requirements of projects in terms of equipments/ space rather than mere capacity expansion, etc.

5.14 Capturing Opportunity in Emerging Markets

In the context of pharmaceutical exports because, as shown by the examples of Thailand[9] and South Africa[10], there are situations when patented pharmaceuticals become too expensive for developing countries and consequently, they import cheaper copies of these drugs. Indian companies such as *Cipla*

[9] The Economist, "A Gathering Storm", June 7th, 2007. This mentions initiatives by Malaysia and Brazil to pursue compulsory licensing.
[10] The Economist, "The Price of Africa's Cheap Drugs", April 19th, 2001.

and *Aurobindo* have been at the forefront of exporting drugs in these situations. It is an acknowledged fact that India has requisite manufacturing capacity, internationally approved quality and regulatory infrastructure in several companies. Diseases like AIDS etc are national emergencies. Since India is one of the countries which has significant manufacturing capacity as well as a past record of providing for such situations, an important opportunity as well as social responsibility emerges. [11]. For example India has offered various ARVS (Antiretroviral) such as NRTIs, NNRTIs, PIs at a breathless speed and at affordable price. Various international organisations and governments which did not dream of providing medicine except for campaigning prevention could benefit from India and are able to provide relief to millions in Africa etc. A simple look at WHO approved ARVs or PEPFAR approved ARVs clearly illustrates the undeniable contribution of India in controlling AIDS internationally at affordable cost. Indian organisations like Aurobindo have been felicitated at White House and at UN for such contributions.
Emerging markets pose several challenges to exporters. A. cost of reaching them to start businesses, registering products etc., B. low volume requirements for several products, necessitating a large portfolio for commercial viability. C. several varying technical and non technical barriers D. credit risk. On the contrary the advantages are also many. A. the domestic industry in several countries is weak B. the current financial and skill requirements for setting up cGMP facilities does not justify viability. C. the regulatory aspirations are increasing and there is a room for high quality companies to replace old firms with dated technologies and systems. D. the market achievements can be sustained over a longer period.

India should assess each country opportunity and develop a strategic plan in terms of, a. Required product portfolio, b. suitable export firms portfolio to register and produce these products, c. credit strategy that can be incorporated in bilateral trade relations as a country credit instead of credit risk being taken at firm level, d. procurement strategy to facilitate registrations and govt purchases. The fragmented industry with several small firms finds each opportunity unviable at a firm level and the nation misses the opportunity as a whole. Hence, Banks or pharmexcil , may facilitate cooperation at firm level to pool the products and share costs in overcoming the initial costs before exports commence.

The issue of capital and output ratio is a national subject. The capacity building has taken place with funds from Indian Banks and Indians as share holders. From a highly centralised license permit regime, we have moved to a free economy very rapidly. However our firm level capabilities to understand the markets, global demand, legal issues, etc are highly skewed. While leading firms employ international consultants and obtain knowledge, majority of other firms do not have access to requisite knowledge . For example, due to such lack of global market intelligence and dynamics, in some categories like cephalosporin's, Indian firms have built large capacities where the global demand is a fraction of what we have built .These are natural perils in a free economy with inadequate evolution of modern business systems. The fragmented industry can ill afford modern business practices at firm level. While it is unthinkable to monitor investments in each sector in our free economy, it is a national requirement to

[11] Duncan Matthews, "WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem?", 7 J. Int'l. Econ. L. 73, (2004).

overcome the economic weakness at firm level through shared concepts facilitated by govt bodies in the interim.

Thrust in developing Economies

Neglecting less developed markets may prove unwise in medium term. We should develop customised promotional programmes for markets in Africa, CIS, South East Asia and Latin America more vigorously. Non tariff barriers are constantly mounting in various parts of world. Although these markets are less regulated, the regulatory requirements and aspirations are escalating. Many current exporters in various countries with compromised infrastructures will find uneconomical to reinvest in businesses paving way for growth of Indian Pharmaceutical industry with high quality investments in manufacturing.

One key barrier is cost of product registration and consequent follow up for our highly fragmented industry. We have to go out of box and facilitate a shared structure to provide skilled registration services for our fragmented industry to capture the skill set , minimise costs through economies of scale . This will provide a breather to SMEs who have already invested heavily in manufacturing and finding it difficult to economically register and reach various markets. Learning the skill set and regulatory compliance issues for each and every country across world are prohibitively expensive for a SME. However such a draw back can be overcome with a public initiative in providing such service. The skill set achieved can be available for multiple organisations. Further procuring RLDs (Reference Listed Drugs) or Innovator samples across world is a very expensive and time consuming process for a SME. A shared service set up can overcome this barrier.

Pharmexcil can organise India trade meets in several countries bringing together Indian SMEs and corporates and local buyers aggressively.

Shared Regulatory Services

Pharmexcil should develop an umbrella regulatory services department wherein each SME or small corporate need not liaise with the local governments independently for drug registration. Such a cooperative setup will be nodal point to register products for various companies into the destination country on a shared cost basis and help acquire strong skill set, utilizing local experts in the country, avoiding duplication of resources by our highly fragmented industry. Such an entity can help do quality filings and hasten the exports at minimal cost.

Shared Marketing Services

Where feasible, Pharmexcil can facilitate marketing co-operatives in destination countries, wherein a common co-operative entity can market the products for its members at a small

marketing fees while remitting the entire revenues to the respective exporting member companies. This will help the co-operative enjoy larger product portfolio, large capacity as a backbone, economise of scale in distribution and warehousing, etc. and minimise the overall investments in the marketing.

Identifying Strategies to Participate In Regional Clusters

In each regional cluster in the global pharmaceutical trade there exists a country in each cluster which supports all the neighbouring countries. Currently India competes with these regional champions in exports to the countries in the cluster. Over a period of time as regional champions emerge our exports could dry up. Pharmexcil should organise a study with the objective of finding practical strategies in utilizing these regional strengths for the furthering of our exports.

Anti-diversion Mechanism

Indian companies should be careful to have anti-diversion mechanisms in place i.e. mechanisms to ensure that the medicines are consumed in the market for which they have been manufactured (the market which has declared the national emergency) and are not re-exported, as this would tarnish their reputation irretrievably. Pharmexcil should initiate a system with exporters wherein it creates awareness and promotes compliance.

6. Building Contract Manufacturing Industry

6.1 Contract Manufacturing Opportunity

Three major developments suggest that Indian drug manufacturers are set to benefit from an outsourcing boom. First, an upsurge is taking place as a number of top-selling drugs come off-patent in the next 5years and the pressure on profitability and differential in cost structures are expected to force the Pharmaceutical companies to outsource (refer table 21 & chart 20). Second, after India has become TRIPS compliant, the discussion is what to source to India than whether to source. India's capability with respect to APIs or formulation production cannot be ignored. Although it is painful to shut down plants or shift products to either India or China, today's CEOs have no choice other than reducing the overheads of their local manufacturing divisions.

Table 22: Comparison of Cost Advantage in India (%)	
Costs in the Western Countries	100.0%
Production costs	50.0%
R&D Costs	12.5%
Clinical Trials Cost	10.0%
Source: Pharmexcil Research	

The global market for contract manufacturing of prescription drugs is estimated to increase from a value of $26.2 billion to $43.9 billion, although the over-the-counter medicines and nutritional products sector will show the fastest growth. Asia has recently been challenging North America and Europe's traditional domination of the global pharmaceutical contract manufacturing market. India and China could potentially account for 35 percent to 40 percent of the outsourced market share for active pharmaceutical ingredients, finished dosage formulations and intermediates.

India's entrepreneurial pharmaceutical manufacturers are now beginning to leverage benefits from the introduction of the nation's product patent system. Although, most will be unable to develop the financial muscle necessary to embark on R&D for innovative new products, but the scientific, technical and manufacturing skills, developed under the country's 35-year process patent system, perfectly matches the requirements of global drug manufacturers who are increasingly seeking to offshore many manufacturing activities previously performed in-house.

Indian successes in this area have already created some significant international developments. Several Indian firms like Jubilant Organosys, Dr Reddy's, Nicholas Piramal, Shasun Drugs, Bilcare, etc, have made acquisitions in this area.

Pharmaceutical production costs are almost 50 percent lower in India compared with western nations. India's long-established manufacturing base also offers a large, well-educated, English-speaking workforce, with 700,000 scientists and engineers graduating every year, including 122,000 chemists and chemical engineers with 1,500 PhDs. These English speaking capable science graduates or postgraduates can be employed on the shop floor in India as Indian manufacturers can afford them. The understanding of chemical/manufacturing processes is so good that India has won significant number of regulatory approvals from world's best agencies.

However, unlike IT services, it is difficult to shift Drug manufacturing activities from existing locations to India. A product outsourcing or relocation decision means approvals of the product from the new contract facility, necessitating substantial costs and investment in lot of scientists' time in proving the equivalence, in each and every country where the product is approved. This by no means is an easy task. However, there are compelling reasons to outsource, such as significantly low manufacturing costs or cost of refurbishing obsolete facilities or shut down decisions due to patent expiries of branded drugs. Obviously, such market capture although is tedious it is long lasting. India's competence with regulatory skills and other technical and human resource capacities qualifies it to capture the first movers' advantage in this respect.

Although the opportunity is very large, currently the sector is dominated by only API business deals. Global leaders need considerable capacity at a single unit to outsource formulations. For example, if a company out sources ten formulations to ten plants in India, all ten will require inspections by several country regulatory agencies and it is considerably expensive and risky. As global leaders' requirements are huge, outsourcing capacity available for such companies is inadequate at a single point. This is the reason that the Industry has been investing heavily on capital expenditure in the last few years in augmenting their capacities.

Practically all economies with either high wage cost for scientific staff or having insufficient population and consequent economies of scale are willing to outsource from India. In the API segment, issues are less complicated and the sourcing is intense. In the long run integrated services of supplying APIs as well as formulations will help manage inventories, logistics and cost structures. Capacity building, Increased testing laboratories for stability studies, bioequivalence studies and third party analytical laboratories will draw contract manufacturing to India than China.

Investing in Key Links to Accelerate Outsourcing Business

Government should promote capacity building in testing laboratories for stability studies, bioequivalence studies and third party analytical laboratories urgently through policy action, appropriate incentives and venture capital. Such facilities can be made available to SMEs at subsidised rates to reduce entry barriers and encourage competition from start-ups in drug discovery and other key growth segments.

6.2 Challenges for Contract Manufacturing Industry

By its nature, the contract manufacturing segment needs intense capital expenditure, high scientific skills in managing regulatory compliance and meeting international environment standards. The decision of outsourcing in large corporates is a serious one and it has to meet corporate objectives along with economic motives. There are several tax efficient locations in world and the segment is well understood by China as also by certain European nations. However, once contract manufacturing moves to the country, the business is secure for several decades. This aspect has to be understood and necessary concessions have to be given.

API and formulation SEZs consciously built will be able to compete in the global market. Due to peculiarities of the industry, it takes three to four years to set up the facility, validate it, get inspected and obtain marketing approvals. The costs in terms of filings, inspections, government fees for products, etc., continue for several years until a broad portfolio of products and markets take place. The commercialization is slow. Generally a twenty year business view is taken for such decisions.

Promoting SEZs to Accelerate Contract Manufacturing

SEZs should be promoted consciously in the area of formulations and APIs to ensure that Indian industry compares at par with international locations.

In reality contract manufacturing means inputs for conversion are given by the third party and the processing charges only are actually billed. However, in India in reality the inputs are purchased and imported by the contractors and finished drugs are sold to the concerned party again. The customs clearance permit bond system needs to be reviewed as it has not helped contract manufacturing for a variety of reasons. In this system, the working capital burden is intense for the contractors. Moreover, while developing a new location, MNCs cannot change the locations of input and output at the same time. Hence, inputs come from the current approved locations while the output location changes. Subsequently, there will be motivation to change the input location also to India. There are procedures

available to do real contract manufacturing in international market, where inputs come from outside and go back after conversion.

Resolving Hurdles in Contract Manufacturing

The Government may look at developing a practical and operable system, which should be adopted by contract manufacturers where in the goods come for processing without paying any duty and go back with out any duties except for the processing costs or value addition. The system should have compliance of Drugs & Cosmetics Act as such manufacturing requires lot of documentation meeting the regulatory requirements of various destination countries. Typically, the inputs come from a country and the output will have to go to several countries. Even in standard contract manufacturing, there are issues of free sale certificates, etc. hence there is a requirement for an interdepartmental action to appreciate the issues involved and develop appropriate departmental notifications.

Another important challenge is the lack of bargaining power with respect to various obligations imposed in agreements. For example, in the current structure, the manufacturing and compliance responsibility lies with Indian contractor. There are natural business risks like inspection failures or supply failures, etc. Many small scale or medium scale manufacturers do not have enough legal acumen or access to legal capacities to understand the issues in various clauses such as reputation damages, consequent damages, price fluctuations guarantees, etc.

Pharmexcil's Role in education on Intricate Issues in International Contracts

In the interest of manufacturers, Pharmexcil should develop standardized agreements and caution on various clauses and their implications to the firm in the long term. A one time effort employing international experts will raise the standards of understanding in this regard.

In the context of contract manufacturing, economies of scale are achievable when certain product or product groups are produced for various countries. In this context, unlike past, the same product gets registered in different countries in different forms in different brand names or in different colours or shapes as per the strategies of the international firm. The contractor stands a good chance of economies of scale if the firm can source applications of the product from several firms to increase production volume. In this context the same product may need multiple brand name or generic licenses for different firms matching their individual needs. Each importing country demands free sales certificates, CPP, etc. Necessary clarifications or orders empowering regulatory bodies should therefore be undertaken. If required appropriate changes in law may be made.

Often high level executives of importing organisations from various countries visit facilities before giving business. In China, governmental representatives are commonly invited when major buyers visit. These government representatives assure international businessmen in case of any aspersions on infrastructure and conditions of production and some times resolve difficulties expeditiously. There is a perception problem in the minds of global business men over handling of bureaucracy. A proactive role for the government in this sphere is clearly made out.

Often contract manufacturing relationships with big firms may take up significant management time if appropriate positioning does not take place from the beginning. It would be tempting to say that Indian companies may tie up with large multinational companies for contract manufacturing and the same would always be profitable for them. In reality however, the last few years have seen pharmaceutical alliances become more and more complicated, requiring significant resources simply to manage. According to a survey 85 percent of senior officials of the pharmaceutical industry expect the number of alliances to increase over the next few years.[12] In order to enter into an effective partnering with the outsourcer companies, Indian CMOs need to adopt any one of three kinds of commercial arrangements:

(i) Long-term supply agreement for pure contract manufacturing with total transparency in the pricing structure (such arrangement works well with professionally managed long-term players)

(ii) Using the capabilities of the partner for process technology development and utilize their facilities for scaling-up and further commercialization; and

(iii) Work on a contract research basis with laboratory space dedicated to the purpose of research on a full time equivalent (FTE) basis, where the innovator has the complete freedom of research design and process (such arrangement works well when the Indian partner is capable of providing world class infrastructure at a competitive price)

Intricacies in Negotiation of Contract Manufacturing

Pharmexcil should organize learning module on contract manufacturing negotiations and help small and medium scale entrepreneurs appreciate the issues of short term and long term. There exists a case to evaluate whether company law provisions have to be amended to bring in exclusive licensing of substantial capacity on par with hiving-off substantial assets.

[12] Ameet Mallik, Brett Zbar, and Rodney W. Zemmel, "Making Pharma Alliances Work", 2004 (1) *The McKinsey Quarterly*, available at **www.mckinsey.com**.

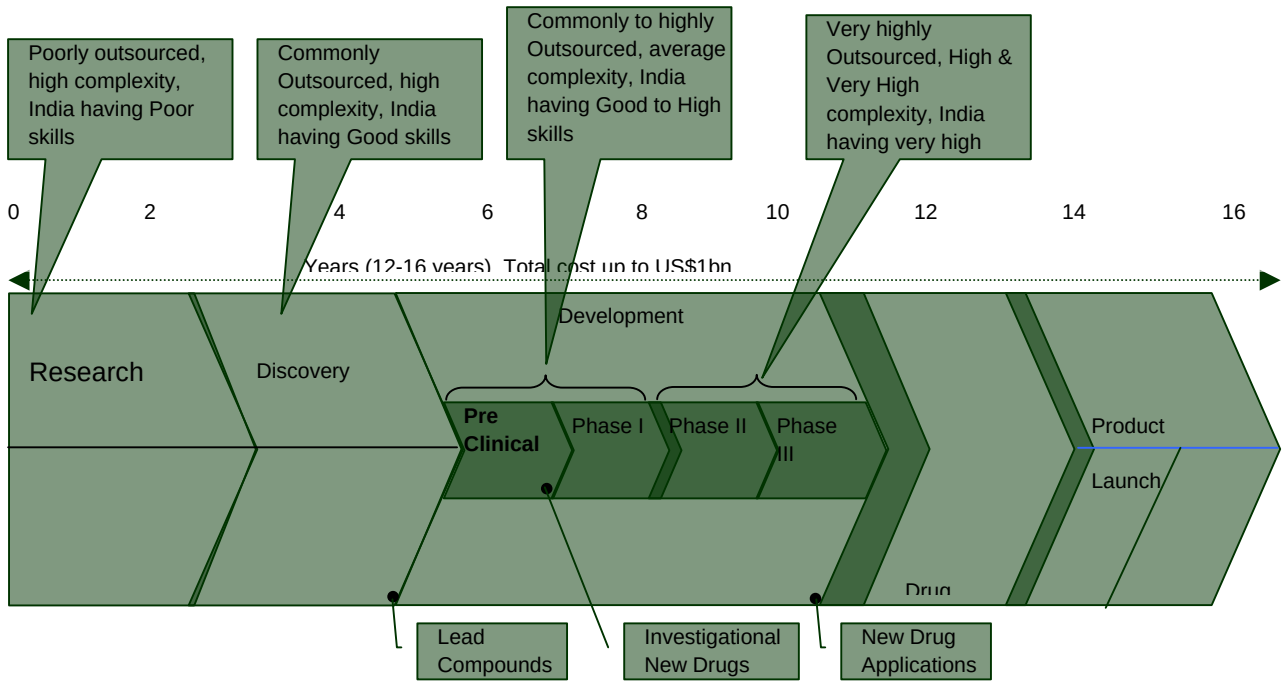
7. Drug Discovery and Contract Research Services

7.1 Drug Discovery Value Chain

New Chemical Entities research is an extremely high-risk proposition. The balance sheet size of Indian pharmaceutical firms is limited and currently Indian pharmaceutical companies cannot afford around US$1 billion required for drug development and clinical trial costs. India's domestic companies have just begun the journey in drug discovery. The country had seen some success in select companies and as expected the number of drug candidates that pass through subsequent phases post out licensing is limited.

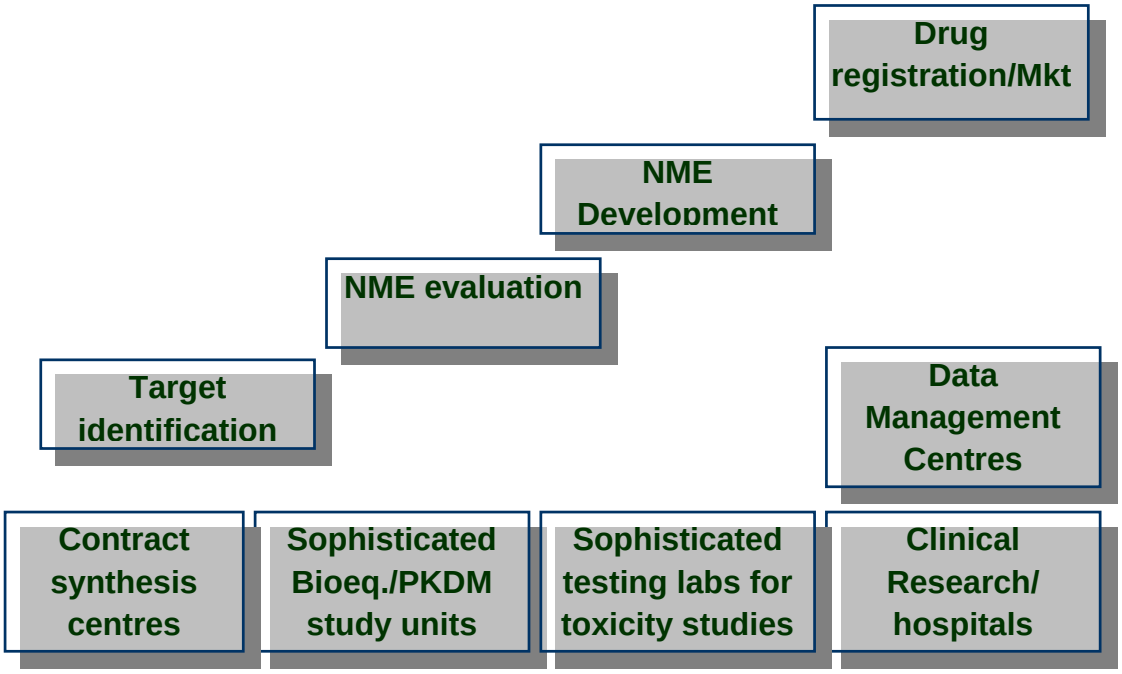
Although drug discovery science is highly developed in the west, India is still emerging in this area. A strategy for developing skills in value chain of drug research could pave the way for success of the country. In the drug research value chain, there are key blocks like biology, chemistry, drug evaluation, preclinical trials and clinical trials (refer Exhibits 3 & 4). Building the skill set and investing in the infrastructure to achieve critical mass will help draw the research work into the country perhaps in a piece-meal initially. As the components get built, entrepreneurial initiatives will kick off on a broader scale, establishing the industry.

Exhibit 3: Drug Discovery Value Chain



❖ Develop workable hypothesis linking drug target with disease	❖ Identify product with high likelihood of improving disease outcome	❖ In early stages, generate safety and efficacy information on a smaller number of patients to improve decision-making before full development ❖ In later stages (full development) develop product by testing a larger (statistically significant) number of patients to obtain drug registration	❖ Obtain permission to market the product	❖ Raise awareness of new drug among prescibers and gather additional information regarding efficacy and possible adverse drug reactions
Source: Zinnov Analysis				

Exhibit 4: Key Areas in Drug Discovery



China has significant width and depth through public initiatives and India is moving in this direction. China appears to be building key components successfully to smoothen its foray into drug discovery. Almost all of the top twenty multinational Pharmaceutical companies have outsourced chemistry work to China. Some Chinese companies have bought/established laboratories and others have collaborated with government institutes like Shanghai Institute of Materia Medica. Preclinical and biology activities are interesting opportunities and China outpaces India in innovative biology. Life sciences research has evolved mainly in China in the state funded research institutes which are heavily sponsored by

government of China. Reports indicate that China's biotech is almost totally underwritten by government. Over 60 life-science parks are trying to carve into shape in China. In fact, China is offering amenities and fiscal/regulatory incentives to multinational companies perhaps to increase domestic skill sets. Over 100 companies offer biology research services. Its successful research in stem cells, biochips, gene sequencing is notable. Over 300 organisations offer contract research services. Further, China has huge domestic market with better pricing and purchase power, which is perceived to be a significant advantage in developing drug discovery projects.

India has been developing rapidly in these areas. Various surveys indicate that India has quite a number of resourceful firms in the field of Chemistry providing high quality output in timely schedules, allowing more leads to pursue. India is significantly ahead in chemistry services such as analog preparation, analytical chemistry, focus library, combinatorial chemistry, structural chemistry, structural drug design, computer aided drug design, high throughput screening and assay development.

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

Through strategic building of infrastructure, such as organizations conducting chemistry research, preclinical trials and clinical trials and later biology research, India can create a strong vendor base allowing various companies in the world to undertake new drug research. Biology research services market and infrastructure should be developed with conscious effort. Such services in all key segments built even in piecemeal will create good vendor base and augurs well in converting the country into an NCE hub. Obviously, such effort will be a successful driver to earn from export of pharmaceutical services. The investments of the industry in basic research may not increase as the profitability of the generic industry are under pressure and there is lot of effort pending in generic industry itself in building broad market/product portfolio.

In this context it is ideal to build the components with focus. Indian skills in chemistry work compares well with that of US/EU/Japan but costs are about one third or one fifth compared with them. In addition, confidentiality, patent protection, English speaking and IT capabilities are significant advantages making India attractive. The global pharmaceutical industry's profitability is also under constant attack as costs continue to rise and prices are under pressure. Soaring costs of R&D and administration are persuading drug manufacturers to move more and more of their discovery research and clinical trials activities to the

subcontinent or to establish administrative centres in the country, capitalizing on India's high levels of scientific expertise as well as low wages.

Contract research in generic pharmaceuticals is also a significant opportunity (refer table 22 & chart 21). Established generic companies would like to outsource or buy services in formulation development, bioequivalence testing, stability studies centers, etc.

At this point of time although the market opportunity is very big, the industry is very small in size. For example the number of beds available in bioequivalence/trial centers is insignificant compared to the opportunity. There is big shortage for Clinical pharmacologists. The number of approved GLP labs is very few and the clinical investigators are a fraction as that of USA. The established pharmaceutical companies are busy internally with their own work in their facilities and the available facilities for tapping international market is limited.

Table 23: CRO Market-size of India (figs. in US$ mn.)

Year	Market size
2001	12
2002	22
2003	39
2004	70
2005	120
2006	202
2007	323
2008	485
2009	728
2010	1,020

Source: Zinnov Analysis

Encouraging Public Private Initiatives in R&D

Major impetus to R & D should be given through the creation of synergy between the industry and academia where the 'cluster' model of the United States could be adopted. This may be accomplished through policy initiatives which stimulate research partnerships between pharmaceutical industry and academic institutions / publicly funded R&D organisations. Encourage the mobility between personnel from R & D institutions and the private sector.

Intense scrutiny of patentability of research is needed for grant of funds.

Pharmaceutical Research and Development Support Fund may have to be increased in size and clearer policies governing its application could be helpful. Encouraging tripartite partnerships between corporates, lending banks and the R&D fund may bring in investment in desired direction and its better utilization.

Revenue generating and patentable research should be the focus in research. Ensuring some participation of private sector in each project helps in adherence to time schedules and weeds away unattractive projects. The current global recession is releasing several scientific personnel in western world. Proactive steps in bringing experts to India to lead our projects or help us as consultants can bridge the vast gap in drug discovery value chain. Procedural issues in Visas etc. can be resolved for specialists building our national projects.

7.2 Pharmaceutical Incubation Cells for Encouraging Innovation & Entrepreneurship

Innovators / risk takers by aptitude with an integrated science background would like to test their concept / work with their own hands to see their thought process is in line for a break through. They would toil around in data mining and come to a novel (out of the box) thought. They lack the resource to create a facility or have patience to work in organized set ups. They need a plug and play facility, without need to bother about discipline or infrastructure. They learn quickly what not to do or to do to materialize the novel innovations. They would eventually inherit the leadership traits. They need a ready available space/ workstation for experimenting and support in analysis to prove the concept. This is to true even in case of knowledge applications such as Biocatalysts / enzyme activities/ mutation/organic synthesis/novel formulations/ liposomes, etc.

Such innovators need to be encouraged through providing working stations similar to a chain of microbiology laboratories with separately managed common facilities. India needs several incubators in key cities for young scientists to experiment their concepts and encourage the innovation and entrepreneurship. Such incubators shall charge variable costs like rental charges for using the workstation and incubator. These incubators can have variety of equipment and modules required to convert a concept to a proven test.

These incubators can be organised under NIPER. These incubators can be called as innovations centres.

R&D Incubators to Promote Entrepreneurship and New Ventures

BOT (Build operate Transfer) model in the lines of public private partnership could be considered to create a conglomerate to have 20 to 25 workstation in each incubation cell in each incubator. Such incubators in all major science cities such as Hyderabad, Bangalore, Pune, Chennai, Chandigarh, etc. under the aegis of NIPER may be promoted. Common storage, air handling, water, effluent management, analytical support is part of infrastructure. Depending on the location a capital out lay of Rs.5- 10 Cr may be required to revolutionize this concept.

8. Fostering Indian Clinical Trials Industry

8.1 Clinical Trials Opportunity

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

Costs of clinical trials in India are around one-tenth of their levels in the U.S. and it is estimated that they could be worth US$300 million to India by 2010. Major drug producers that are already conducting trials in India include Pfizer, estimated to have some 20 ongoing clinical trials; GSK, with seven trials; Eli Lilly, with 17 trials; plus AstraZeneca and Novartis as well as Chiltern. Leading contract research organizations (CROs) such as Quintiles, SFBC International and ICON Clinical Research have extensive operations in India.

Currently, India is experiencing a growing number of collaborations between Indian and foreign firms in the domestic market, especially involving the biotechnology sector, in a wide variety of areas such as collaborative R&D including drug discovery and clinical trials.

R&D often gravitates to countries with large domestic markets for the resulting products.[13] In this case, India's GDP growth has not been as high as China's, hence it cannot offset China's advantage on pure spending power. However, India will continue to have a significant advantage over the next few years, due to its proficiency in back office work, etc.[14] Component break-up of R&D are presented in Table 23 & Chart 22 below.

[13] Diana Farrell, Noshir Kaka, and Sascha Starze, "Ensuring India's Off-shoring Future", 2005 Special Edition, *McKinsey Quarterly*, available at **www.mckinsey.com**.
[14] *Id.*

Table 24: Composition of R&D Budget of Pharmaceutical Companies		
Sl. No.	**Item**	**%**
1.	Clinical Development	**38.2%**
1a.	**Phase - 1**	18%
1b.	**Phase – II & III**	67%
1c.	**Phase – IV**	16%
2.	Discovery	**26.9%**
3.	Non-Clinical	**19.5%**
4.	Regulatory	**4.1%**
5.	Others	**11.3%**
Source: Zinnov Analysis		

8.2 Challenges and Potential Solutions

Scarcity of specialist clinical pharmacologists, clinical investigators is most critical issue facing Indian clinical trial industry.

Enhancing Availability of Clinical Investigators/Researchers

India should attract Indian scientists to set-up service centres in India and provide Venture Capital funds on some prioritization basis.

Efforts should be made to coordinate with medical colleges and pharmacy colleges to enhance focus and seats in clinical pharmacology.

A study may be organised for examining the opportunity to set up a discipline for clinical research or a special training to become clinical investigators.

To carry out clinical trials successfully, Indian firms need expensive infrastructure facilities such as hospitals with modern imaging technologies, facilities like world class Biochemistry Laboratories, X-ray Units, CT/MRI scans and round-the-clock availability of specialists. Unlike a manufacturing industry which has more flexibility in choosing the locations, clinical services providers require space and infrastructure at a convenient location close to general population. Hence, in addition to infrastructure, considerable real estate costs become a burden. India needs to attract large medical hospitals and institutions to enter this arena. These hospitals and institutions understand the equipment and can create space. By declaring commercial clinical research, bioequivalence studies research, etc., as an R&D investment eligible for tax incentives, the country can draw these institutions to set up these incremental activities. Pharmexcil could engage in information dissemination activities to the potential institutions.

Enhancing Capacity for Clinical Trials, Animal Toxicity/BE centres

Standardised project reports on building service centers should be developed and current medical institutions and hospitals should be motivated to evaluate setting up of such infrastructure.

Clinical trials, bioequivalence studies, various toxicity study centers contributing in drug discovery work could be unambiguously termed as R&D investment eligible for tax holidays and weighted deduction.

Drug discovery firms cannot do all work in house and they need to outsource some of work like testing, etc., to third parties. Such outsourcing portion by a government approved R&D facility should be considered for weighted deduction. In the absence of this, each firm has a miniature service center for its own purpose and the sector can not develop and skills required can not be institutionalized.

India, in order to successfully undertake clinical trials needs to employ a greater number of proficient Institutional Review Boards (IRBs), having professional competence in addition to knowledge of international and national regulations, applicable laws and standards of professional conduct and practice.

Government Body Should Facilitate Learning and Legislation with Respect to IRBs

A course familiarizing Institutional Review Boards (IRBs) could be designed and the information should be communicated to eminent eligible people retiring from various service sectors. By attracting them to understand the opportunity and familiarizing them with the subject, the country can enhance pool of available experts to help these boards.

Incentives to CRO

The incentives mentioned in the draft National Pharmaceuticals Policy of 2006 such as exemption of service tax for direct investment in the field of clinical development and data management, exemption from import duty, improved regulatory infrastructure and some form of protection for undisclosed test data, etc., ought to be acted upon.

Clinical trial samples imports and exports are currently heavily regulated. Each clinical trial specimen samples exports require approvals from DGFT, DCGI, etc. International clinical trials will need certain

portion of specimens to be tested in certain central laboratories as a procedure of validation of trials. The current approval system requires several weeks of lead time, which is not conducive for commercial business. In addition, consignment to consignment approval system is causing avoidable time delays. Lot of clinical trials involve new drugs and often they will be in the chemical name. Importation of these samples for clinical trials activity with chemical names, etc., has dimensions different from conventional imports of drugs.

Simplifying approval procedures for Clinical Trials Export/Import Materials

Established/accredited CROs should be permitted to take one time clearance for import/export of clinical trail materials if the parties to the contract are the same avoiding repeated clearances from various agencies. Based on risk profiling approval from single agency should be considered as time element is most crucial in obtaining and executing of contracts.

Companies engaged in stability testing will have to test large number of samples and import duty on these consignments will kill the business. An approval from DCGI declaring that such samples for research on a case to case basis can cause the waiver. It is not practical to procure licenses in a timely manner to import them for testing in the expected time frame. Analytical testing like stability testing etc are good opportunities despite our handicap of distance and transportation. Government may draft necessary legislation keeping the new dimensions and opportunities in the pharmaceutical business . Extensive decentralisation and online approvals are essential. Self approval facility should be given for established corporates based on some risk profiling and audits.

Contract research organizations in chemistry service need scale to attract interest of the buyers and such organizations are capital intensive with long payback period. By leaving the segment to follow its natural course, the industry may not develop in the desired direction. For example, biotechnology industry is characterized by thousands of firms with average size of employees less than fifty. Often university professors, scientists, etc., start these firms and develop some targets. Such targets after screening get licensed to big pharmaceutical companies for development and commercialization**.**

At current interest rates and real estate costs, setting up such facilities, establishing credibility and sourcing business demotivates either established organizations or new start ups to get into this area. However for India's strategic purposes, this component is very vital.

Contract research of large scale should be taken up by some existing firms with financial muscle. Commercial R&D firms have to be independent firms to avail tax advantages. Hence, these large companies cannot avail tax holiday in this area by setting up a division or subsidiary. Completely independent companies often face capital sourcing problems. The services from these independent

companies will attract service tax incidence. Further, outsourcing to these firms by the parent company research department make them lose weighted deduction advantage. Hence spin offs from major companies to boost this sector is unlikely. Spin offs from companies will help focus and specialize in those areas which can go for economies of scale and global business sourcing.

Service Tax Exemptions for pharmaceutical R&D

R&D services may be exempted from service tax net for national priority sectors. Providing drugs for Indian citizens is a big priority for nation and this sector could be waived from the net.

VC Funding for CROs to Promote Value Chain in Drug Discovery

Prioritised Venture Capital based funding should be provided to set up large contract research organizations.

Large scale stability testing, Animal toxicity testing services is a very attractive opportunity for India. For example, every drug needs stability data over a long period of time. Corporates outsource such activity. The CRO has to be reliable and should conduct stability studies for the agreed period and retain the records for several years. Large scale stability studies center will have economies of scale like any IT organization. The skill set required is standard and the process is mechanical. However, the cost of setting up such centers is capital intensive. India should consciously draw varieties of R&D activity pieces into the country. Outsourcing of API synthesis, API production, formulation development, formulation manufacturing, analytical testing, stability testing, animal toxicology centers, etc. are various pieces involved.

Pharmexcil/government departments should meet up corporates and push for setting up of large scale stability centers which does work for multiple organizations. This will be a conscious step in building economies of scale in an otherwise fragmented industry. Also, such step will help SMEs to avoid huge capital expenditure involved in maintaining stability.

Samples imported for stability studies should not carry any import duty. These samples get analysed and there will be no re-export to set off the duties. In the global analytical market there is no room to bear the country's import duties. As the market is new, our current laws need to be fine tuned to accommodate these areas. State DCIs may be empowered to give permissions of duty free imports of stability samples from foreign clients.

Analytical testing is a very important piece in the building of contract services industry. Analytical testing industry is dependent on both availability of chemists and capital investments in analytical instruments.

Our country is a good candidate country to obtain a good market share in the global market. However, the proximity to market is an important dimension in the sourcing of business. In spite of the disadvantage, lot of analytical testing, method development, method validation and other services can move to our country.

However, import of samples for analysis requires speedier arrival of samples, the reference drugs, etc. In the current system of every thing needing approval from DCGI such as reference drugs, import of samples etc., the business is experiencing abortion in the womb itself.

Decentralisation of Approval System

There is a need to decentralize the approval system (e.g., State DCI approval) of T licenses for already approved drugs in India. Automatic approval may be given for new drugs for "invitro testing work'' or if the testing is not in humans (e.g., State DCI). The bottlenecks in importation of blood samples for analysis have to be removed fast. Risk profiling should be done and reputed clients and reputed service centers in India should be given exemptions with obligation to submit annual reports.

Most countries require some highly standardised documentation like COPP, FSC, etc. If a company has fifty products registered in fifty countries, the firm will have to get almost 2,500 certificates from DCI offices. Although it is simple, it is avoidable waste of time. Such certificates should be available on line for substantial exporters. A fresh guideline and procedure should be issued by Government removing unnecessary approvals and procedures. Testing services is a time bound activity and competes with established players. We have inherent disadvantage of distance and shipping costs. In addition, if there are too many procedural delays and requirements, a significant opportunity is lost. In addition, the opportunity to become a global hub for pharmaceuticals require successful large scale infrastructure in various links that build the chain.

Such certificates should be available on line for substantial exporters. Or a drug control office employee empowered to sign such documents should be posted at where there is a huge requirement of procedural documents.

9. Indian System of Medicines

This report refers to the phrase – "Indian System of Medicines" ("ISM") as including Traditional Medicines, Ayurveda, Unani and Siddha systems of medicine. For convenience, throughout this text we have used the acronym AYUSH to denote Ayurved, Unani and Siddha systems of traditional medicine prevalent in India because of the use of this acronym in common parlance. This section of the paper also looks at the export of medicinal plants from India, because at present the ratio of export of finished products to raw material (i.e. the medicinal plants) is about 40:60[15]. ISM's include many different categories of products and while an attempt has been made at their categorization below, ISM's include everything from over the counter formulations to herbal remedies to prescription drugs.

This report attempts to address several of the problems which inhibit the growth of exports from this sector, such as unsustainable cultivation practices for the ingredients of AYUSH medicines, non-recognition of AYUSH as valid medicinal products, absence of specific AYUSH driven good manufacturing practices, unclear guidelines for gauging quality, specific fears such as biopiracy and inadequate benefit sharing policies in Traditional Medicines, Non Tariff Barriers, inadequate awareness in target markets, etc. While not an exhaustive list these are indicative of the factors that are holding back exports of a sector with good potential.

9.1 Background of AYUSH Industries in India

There has been a great deal of interest in alternate remedies for some time now,[16] as illustrated by measures such as the Work Programme for the European Medicines Agency 2007, which identifies greater co-operation with India - especially in the field of traditional and herbal medicines and remedies.[17] However, alternate remedies are not necessarily the same as AYUSH and there are serious information gaps, which need to be addressed in target markets before AYUSH becomes acceptable as a form of medicine. In India, the AYUSH industry is of no uncertain heritage and can trace its history to the ancient texts which form the basis of this branch of medical knowledge. These texts are listed in Schedule 1 of the Drugs and Cosmetics Act, 1940.

Though the precise figures of recent AYUSH trade are unclear, in 2006 the exports of medicinal plants and plant based products were in the region of Rs.800 Crores. The ratio of raw to finished products was about 60:40. This is a worrying figure for India in light of earlier figures. In 2001-02 the figures for exports were in the range of US$133.28 million and at that time 70 percent of products were plants or plant products whereas the remaining 30 percent were finished products. At that time i.e. in 2001-02 it was

[15] Technopak report prepared for APEDA, "Export Promotion of Medicinal and Aromatic Plants", January, 22, 2007.
[16] World Health Organization, Fact Sheet No. 134, *at* http://www.who.int/mediacentre/factsheets/fs134/en/ (revised May 2003).
[17] Work programme for the European Medicines Agency 2007, EMEA/MB/428793/2006/EN/FINAL, as available at **www.emea.eu**.

envisaged that the ratio of raw materials to finished products ought to be reversed within the next five years. The fact that the ratio remains worryingly weighed in favour of export of raw products suggests that any of the following or a combination of the following broad factors are inhibiting exports of finished products.

- Issues of technical up gradation of domestic industry.
- Non-facilitation of export.
- Issues with market access in importing markets – and this would include issues such as non-tariff measures, non-awareness of target markets, etc.

India's most important competitor in the realm of medicinal plants as well as alternative medicines is China, which is also the largest exporter of such products in the world. The most important markets for export are Hong Kong (which is also a major re-exporter), Germany, Japan, France, Korea, Italy and China.

9.2 Categorisation of AYUSH Products

The precise classification of AYUSH products has been one of the stumbling blocks to the increase in their exports. The classification of the products, determines the regulations to which these products are subjected, in the different export markets. There are possibly two methods of classification. Consultations with prominent members of the industry seem to suggest that one broad division is between the herbal and phyto-chemicals section and the producers of ASU (Ayurveda, Siddha and Unani) products. Members also suggest that the former seems to be set for a very rapid expansion over the next few years, whereas the latter will require innovation from within, as well as favourable regulatory structures through governmental action to achieve high growth levels.

Broadly, AYUSH products may be classified into the following categories[18].

1. OTC products: This would mean over the counter products, which have a consumer demand potential. (e.g.: imago, etc.)

2. Ethically Promoted Products: These are products, which would be patronized by modern medical practitioners as well as Ayurvedic Physicians and have a prescription demand.

3. ASU Classical Products: These are products that are patronized by traditional practitioners of ASU sciences. (This category, as well as the category referred above is dependent on a structure specializing in the delivery of ASU healthcare. Consequently the export demand for

[18] As per the ADMA.

these products would not be as much as the others – simply because most other countries would not have as many certified ASU healthcare professionals).

4. ASU foods: This category includes specific foods as properly called, as dietary and nutritional supplements, organic teas, etc., – i.e. intended for oral consumption.

5. ASU Cosmetics: This would include cosmetic and beauty products, as different from the OTC category and include miscellaneous products such as massage oils, etc., which may have therapeutic qualities in addition to being used for cosmetic application.

6. There will, inevitably, be overlaps between categories 1, 4 and 5 but it is also clear that these are the categories with the greatest export potential. Apart from these finished products, a large number of medicinal plants are also exported by India in the form of raw materials for either re-export (from Hong Kong, Germany, etc.,) or for the herbal medical/cosmetic industry in the importing countries.

9.3 Regulatory Structures

The regulatory structure governing ASU products in India is divided between the regulation of the products themselves and the regulation of the institutions which either train the personnel in charge of training doctors in AYUSH, or are concerned with delivery of AYUSH healthcare or in some cases, both.

Chapter IV A of the Drugs and Cosmetics Act, 1940 (the "Act") governs these products and they are defined in the Act as including all medicines intended for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals and manufactured exclusively in accordance with the formulae described in, the authoritative books of Ayurvedic, Siddha and Unani (Tibb) systems of medicine specified in the First Schedule to the Act.

Legally there may be two kinds of ASU medicine. The first is the kind defined above – i.e. all the classical formulations mentioned in the approved ancient texts and the second is the category of proprietary medicines which are formulations evolved by the manufacturers with such ingredients as are mentioned in the approved classical texts.

Though the Act classifies AYUSH products as medicinal products for regulatory convenience (regulating manufacture on a commercial scale as well as regulating sale through pharmacies against a prescription), many of these products are not only used as medicines, but also as food supplements, or

health foods, or OTC products. However, the effect of the legislation is that any product which is manufactured for commercial sale without a license as required under the Act is not an AYUSH product. Technical implementation/enforcement related evaluation of AYUSH medicines is done by:

- Ayurveda, Siddha, Unani Drugs Technical Advisory Board (ASUDTAB – which advises the government on drug related issues)
- Ayurveda, Siddha, Unani Drugs Consultative Committee (ASUDCC – which advises the government on implementation issues)
- State licensing authorities who actually look after the testing process of AYUSH drugs to ascertain their purity, safety etc.

But this is only insofar as the manufacture of AYUSH products is concerned. The growth of raw ingredients, etc; is governed by different sets of Good Practice guidelines which are discussed later in this Chapter.

9.4 AYUSH Sector – Export Potential

The segments in AYUSH which have export potential can be summarized as:

i. Herbal Extracts/ Phyto chemicals
ii. Ayurvedic Classical/ Generic medicines
iii. Ayurvedic Prescription and branded medicines
iv. Ayurvedic Dietary Supplements
v. Ayurvedic Food Products
vi. Ayurvedic Cosmetics and Beauty Treatments
vii. Ayurvedic Panchakarma therapy
viii. Ayurvedic Practice
ix. Ayurvedic Educational Courses

Each one of the above potential for export requires a unique and focused strategy in promotion. A cursory study of the potential for each of the above segments would indicate great potential for each of the same. Some of the oft repeated factors which indicate good potential are as under:

- World market for Natural Products US $ 62 billion and having double digit growth.
- Market for Dietary supplements growing in both USA and EU markets.
- More than 70% of population in developed countries have tried and regularly depend on Natural products for health care solutions
- Chinese medicinal products and practice have found good acceptance in majority countries of the world

- India possesses the distinction of being called the Botanical Garden of the world with more than 40,000 species and 16 eco climatic zones.
- YOGA as a science has been well accepted and is gaining firm footing in health care segments in most developed countries.
- Wellness and Wellbeing centres/ Spa's are a growing fancy in western countries.
- There is a definite interest in Ayurvedic courses in curriculum of major US Universities. Diploma courses have been instituted in colleges in the United Kingdom.
- There are more than 200 Ayurvedic Physicians from India who are regularly visiting developed countries and imparting educational lectures and health care advice.

9.5 Sustainable Growth of Medicinal Plants and Herbs

Outreach and acceptability of AYUSH systems is critically dependent on a sustained availability of quality plant base raw material. More than 90% of the species used in trade continue to be sourced from the forests. With the upsurge in the demand of herbal products globally, there is increasing pressure of unsustainable collection and over exploitation of medicinal plants bio-diversity from forests leading to shortages of ingredients for AYUSH products, besides a number of plants facing a threat of extinction. While studies seem to show that importers prefer medicinal plants, which are collected from the wild and organically grown (because of the fears of heavy metals and pesticides in the cultivated varieties), it is also a fact that wild collection is not sustainable as a form of supply of raw materials.

In fact, the European Herb Growers Association (EUROPAM) has evolved a set of Good Agricultural Practices (GAP) applicable to the growth of medicinal plants[19]. However, it is necessary that India specific GAPs are prepared by National Medicinal Plant Board (NMPB) at the earliest. It is understood that the preparation of GAPs has some how got stuck in turf issues within the government. There should be no doubt about the domain jurisdiction of NMPB on the subject and the sooner the matter is addressed the better it would be for the sector.

Domestication and cultivation of medicinal plants, therefore, is the key to meeting the raw material needs of the industry besides offering opportunities for higher levels of incomes, crop diversification and growth of exports. According to a recent study, 960 medicinal plants are in trade of which 178 species are consumed in excess of 100 MT per year. More than 90% of the consumption of the domestic industry comes from forests with less than 40 species being cultivated to any significant degree even though agro-techniques of more than 100 species have been developed. The primary reason is the absence of adequate knowledge about the cultivation practices among the farmers and above all, absence of proper markets.

[19] Available at **www.europam.net/GAP.htm**. Last visited on 8 October, 2007.

The global trade requires products of standardized phyto-chemical composition free from heavy metals, and other toxic impurities and certified to be organic or Good Agricultural Practices (GAP) compliant. This is possible only through cultivation route where chain of custody regime is easier to maintain.

Indian share of the world herbal trade is less than 1%. Even here, the export of herbal products is largely in the form of raw herbs with 2/3rd of the export basket comprising raw herbs. This needs to change considering the US $ 62 billion herbal market.

Government of India has recently launched a central sector scheme in mission mode. The mission is expected to address aspects relating to conservation of medicinal plants, their cultivation and harvesting, and marketing with a view to sustain supplies of good quality medicinal plants for AYUSH industry and at the same time promote medicinal plant cultivation as an alternative option to agriculture. The Mission seeks to develop medicinal plants sector through production of raw material of quality and standardized constituents for use by the AYUSH/ Herbal industry and thereby enhance the quality and acceptability of AYUSH systems of medicine and promote export of value added items for an increased share in the world market.

The Mission would adopt an end-to-end approach covering production, post harvest management, processing and marketing. This will be achieved by promoting cultivation of medicinal plants in identified clusters/ zones within selected districts of states having potential for medicinal plants cultivation and to promote such cultivation following Good Agriculture and Collection Practices (GACPs) through synergistic linkage with production and supply of quality planting material, processing, quality testing, certification, warehousing and marketing for meeting the demands of the AYUSH industry and for exports of value added items.

The institutional arrangement for implementing the major activities under the Mission i.e. technology dissemination, quality planting material, cultivation, post harvest management and marketing will be varied depending upon the organizations/ institutions present in the state covered under the programme and will include cooperatives, incorporated companies, state government undertakings, individual entrepreneurs, associations, producer companies, self help groups, Krishi Vigyan Kendras, etc. for ensuring proper delivery under the scheme. All the activities related to cultivation, processing, marketing, quality assurance and certification will be converged under the Mission for better synergy. State Governments are free to choose their own model, create or orient existing institutions to carry forward the objectives of the Mission in a holistic manner. The experience so far with the implementation of the erstwhile similar scheme has not been very encouraging therefore implementation of the mission activity will have to be very eagerly watched. It is noteworthy that much would depend on the quality of implementation by state governments.

It has been reported that many of the significant Indian plants do not find place in the list of importable herbs in many countries. For example, Bacopa Monnieri (Brahmi) the celebrated brain tonic from India is not in the approved list of European Union importable herbs. Similarly Terminalia Belirica (Baheda) one of the three ingredients in Trifala is not a part of TGA (Australia). Most of the countries have lists of importable herbs as food supplements, flavouring agents, etc. Indian herbs are largely left out for the absence of compiled safety data along with data of their usefulness for healthy living. There is a need to compile such list of non importable herbs which are considered significant for exports and prepare their monographs. It is important that these herbs are not classified as drugs only but where ever applicable also as dietary supplements. A joint effort of the industry and government in a time bound format with dedicated funds is of utmost importance.

Extracts of medicinal plants or phytochemicals constitute the most significant export opportunity in the short run for India. An ABC analysis of the main medicinal plants of India, on a pre established criteria, would help us to pick up 25 odd plants, which can be called 'star' plants, to focus all our attention on them, for export needs in the first phase of three years. This is not to undermine the importance of others but is only a method to focus our attention selectively for better results in short time. The immediate need is to gain a firm ground in the foreign markets explicit in statistics. The Vishesh Krishi Upaj Yojna (VKUY) can come handy in promoting these star plants and their products. The VKUY should also include extracts as well as compounds isolated from the herbs so identified under the star criteria. This will incentivise a gradual move from exports of plants and their parts to their products in the first phase as envisaged in several decisions of the government.

Solvents like ethanol are essential need for processing the herbal products. Various State Governments have very elaborate and restrictive practices in imparting licenses even to the genuine industries. This impedes the growth of the herbal extract industry as some countries do not allow for extracts from other solvents. A special and urgent attention to this road block is needed.

9.6 The Manufacturing Process

In India Schedule M of the Drugs and Cosmetics Act includes the Good Manufacturing Practices that are applicable to the pharmaceutical industry and these have come into effect from the 1st of July, 2005. In addition to these it may make sense for the Indian industry to comply with a higher level of GMP's (if possible) as laid out in the two following international sources.

- A (non-binding) WHO publication called "Quality Control Methods for Medicinal Plant Materials" published in 1998, which has been revised in 2005.
- WHO technical Report Series 943, which are recommendations of the WHO Expert Committee on Specifications for pharmaceutical preparations.

Apart from this there are specific EC guidelines, which address Good Manufacturing Practices for medicinal products.

9.7 Market Access

Most industry insiders seem to think that most of the trade barriers in the developed countries can be surmounted with creation of greater awareness and some industry members have been active enough in the identification of these barriers, as well as having been pro-active in trying to get them removed.

Some of the Non Tariff Trade Barriers which have come to light and prevent the free market for AYUSH products and services can be summarized as under:

- Non recognition of Ayurvedic Practitioners for medical practice abroad
- Non recognition of Ayurvedic Pharmacopoeia
- Absence of established norms and procedures for unique requirements of AYUSH products in major markets such as EU, US etc.
- Absence of GMP standards and therefore dependence on WHO guidelines which may not fully encompass Ayurvedic products
- Unclear guidelines on gauging Quality and Standardization
- Absence of clear policies for Educational courses in AYUSH
- Unsubstantiated fears about IPR with respect to AYUSH medicines

It is widely stated that dissemination and validation of a unique medical system can be best achieved by practitioners of the system. AYUSH has grown over thousands of years through transfer of complex knowledge through ancient and medieval systems of education to finally culminate in present day AYUSH educational institutions. There is a sizeable population in the country which in one way or the other uses AYUSH medical system. Despite a sizeable domestic following we have not been able to assign AYUSH practice a place of dignity and respect in the social ladder of the country. On the one hand, we have eminent practitioners who have acquired respect though may have adopted knowledge through traditional methods, on the other; we have a set of practitioners who are educated in organized institutions. Since, AYUSH system despite its social acceptance has not achieved formal socio-political approval, practitioners associated with the system are still considered less popular.

The first requirement is to elevate the AYUSH system in the formal health care system, not restricting it to a few hospitals and health care institutions, but establish it equally with other systems both in qualitative and quantitative terms. This would necessitate a large number of practitioners and improvement in AYUSH education with better positioning. These two outcomes would lay down the foundations of wide scale acceptance of AYUSH system in India itself. Domestic formal acceptance of the system would generate appropriate environment for these practitioners to go out and carry the wisdom and practice of

AYUSH. Therefore, the first concentration of the Government should be on enlarging the scope of AYUSH practice and improve AYUSH education both qualitatively and quantitatively. This should be followed with efforts to see how AYUSH practitioners can go abroad and disseminate knowledge and information. To begin with, this could be done in countries where traditional medicine has recognition as a health care system. For example, countries in South Asia, Africa, ASEAN, etc., can be taken in the first instance to develop cooperation programmes.

India is in the process of negotiating preferential trading arrangements with many countries and some groups of countries. It may be a good approach to include Traditional medicine as an important constituent in these agreements. Traditional medicinal products could be kept out of respective negative lists and could be traded duty free. Besides parties may agree to allow practitioners of traditional medicines albeit in limited numbers and cooperate on technical issues such as standards, export certification, technical capacities and human resource development etc. First such agreement could be taken up in the SAARC region due to similarity of our systems of traditional medicines.

Earlier, in this section preparation of monographs for star plants have been recommended. Similarly, there is a strong need to hasten the process of preparing Ayurvedic pharmacopoeia for established drugs and constituents. In absence of GMP standards, WHO guidelines are being followed. However, there is need to develop specific GMP guidelines for AYUSH products. Quality assurance is a significant demand of AYUSH importers and should help in establishing credibility of AYUSH products. Therefore, a quality certification for AYUSH products exported from India would establish quality credentials of these products, and is strongly recommended.

An assessment of AYUSH sector gives the impression of an environment with complexities. This to some extent could be because of the multiple challenges faced by AYUSH and multiple activities taking place to respond to these challenges. In the exclusive context of export promotion of AYUSH products an exclusivist approach is necessary. Once our focus is limited to 25 odd star plants, for each of them a flow chart of activities would be easier to prepare and monitor. This would necessitate a substantial amount of house-keeping in the concerned institutions of Government of India.

In the manner of selecting top 25 plants it is also suggested that we may launch a Focus Products Scheme for Top 50 Ayurvedic formulations. Funds must be provided for compiling internationally acceptable Drug Master Files for these products and there must be a concerted push between various Ministries to ensure that these products are allowed market access in all countries. An internal licensing mechanism for ASU industry will enable more companies who meet the basic criteria of quality and infrastructure to manufacture and export these formulations. This will also mark the beginning of formal and supported commerce for ASU industry. This will also announce the arrival of ASU formulations in

the global market for natural products and will do to the ASU industry what Ginseng did to traditional Chinese medicine.

Promoting AYUSH Education

Greater emphasis must be given to AYUSH education as well as infrastructure in institutions imparting AYUSH education.

A possible way of facilitating exports could be to create a single window for clearances for companies wishing to export ASU products.

There is great potential for AYUSH to flourish regionally i.e., in South Asia where there is an existing culture of AYUSH, as well as South East Asia which also has had traditional medicines of various kinds historically. A great deal, however, depends on private initiative and business methods to create awareness and start marketing in these regions. Negotiations should occur in the services sector with South Asian countries to allow AYUSH doctors from India to practice in these countries.

A process of certification (internal and voluntary) might go a long way in convincing other countries of the quality of these products.

9.8 A Look at China

By 2050 the herbal market is expected to reach US $ 5 trillion. China has set up over 15 high quality labs to modernize and develop herbal medicine. It gave focus of researching in specific therapeutic areas like liver disease, diabetes etc. Arsenic trioxide an active ingredient extracted from Chinese medicine is approved by US FDA. Similarly ZT 1 is under clinical trials in Europe. Artemisinin based drug developed by Novartis from Chinese herbal medicine is distributed world over. Several multinationals are attracted to develop herbal medicines.

Departments of Chinese medicines are set up in over 95 percent of general hospitals. Over 500,000 personnel are in Chinese medicine sector. Around 2,500 specialised hospitals, 28 medical colleges focused on Chinese medicine and pharmacology, 57 research institutions in Chinese medicine, over thousand companies producing Chinese medicine, fuel the market. The country has over 70,000 graduates and 1,000 postgraduates with Ph.D. or masters degree. China has established three toxicity evaluation centers and four clinical testing centers. Chinese medicines are available side by side with western medicines in various hospitals across country.

The direction for the herbal medicine has to be given by government at this point of time. The big manufacturers in herbal area are focused on food products like honey or Chyawanprash etc., and the serious herbal medicine is under attended.

It will be desirable to expand the delivery of Ayush healthcare in Public Health delivery institutions through a tiered approach within a fixed time. This will encourage Ayush education while it expands its practice and increases the consumption of Ayush medicines..

Extension of Concessions to AYUSH Products on par with Pharmaceutical Products

The Indian Foreign Trade Policy allows some concessions for pharmaceutical products but makes no mention of AYUSH products as a distinct category. Remedying this could have a beneficial effect on the industry, which requires assistance for large scale technical up gradation. Fiscal benefits granted to the industry for such up gradation, could also act as incentives to the industry.

9.9 Promoting Indian AYUSH & Herbal Industry

In order to promote Ayush industry government could consider the following approaches,

1. **Focus Product Scheme** - Select top 25 plants and Top 50 Ayurvedic formulations and Provide thrust

1.1. Funds must be provided for compiling internationally acceptable Drug Master Files for these products and there must be a concerted push between various Ministries to ensure that these products are allowed market access in all countries.

1.2. The Vishesh Krishi and Gram Udyog Yojana (VKGUY) should also include extracts as well as compounds isolated from the herbs so identified under the Focus product scheme.

1.3. These focus products should have a published information on minimum purchase price and minimum quantity for a minimum period of time to encourage reliable cultivation. Produce from both wild sources and cultivated land should be encouraged independently.

1.4. To achieve desired purity level at various micro units spread across the country may not be economically feasible. Hence these have to be bought at a gross level and routed to select central units for purification to bring them to the required quality standards. Processing zones, near important cultivation areas should be developed where the whole process of adding value to the raw medicinal plants takes place.

1.5. Ethanol availability to recognized Ayush industries producing these products should be on a fast track basis.

1.6. These formulations should be given complete tax concession with respect to excise duty/ vat etc. when priced say less than Rs.5/- 'cost of therapy per day' at therapeutic doses and having therapeutic claims.

1.7. Identify & promote Agri Export Zones (AEZs) for these plants.

1.8. Encourage clinical trial work to establish efficacy/safety and process standardisation of various formulations. Government should conceptualise a project and approach established pharmaceutical companies or established R&D labs, etc. to conduct the necessary research for select Ayurvedic preparations especially the analytical research.

1.9. Provide a meaningful financial assistance (for example Rs. 50 lakhs) as a grant if the product satisfies certain parameters such as:

1.9.1. Complies with guidelines on heavy metal/pesticide/mycotoxin/microbial residues

1.9.2. Efficacy is proven by 2 double blind controlled trials

1.9.3. Analytical/chromatographic methods have been developed which facilitate both qualitative and quantitative estimation of ingredients

1.9.4. Is from sustainably usable plant parts for at least 70% of ingredients.

1.9.5. At least 2 publications in reputed journals of pharmaceuticals on the product.

2. **Creating National Resources in Herbals**

2.1. Schedule 1 of Drug & Cosmetics act lists 57 official Ayurvedic books. Many are out of print and these should be made available and digitized. List of Ayurvedic herbs of India as mentioned in these books should also be made available.

2.2. Compile a comprehensive national database on the available scientific information about safety efficacy, phytochemistry and clinical data on each Indian medicinal plant. Create a national library of primary phytochemical reference standards and cost effective testing of herbal products.

2.3. Government should initiate specific research programs through state agricultural universities aimed at searching, identifying elite species/ varieties/chemotypes of those medicinal plants whose quality assessment criteria have been standardized. Herbal extract/product manufacturers having access to high quality raw material (elite varieties) become very critical for maintaining economic viability/competitiveness in both domestic and international markets. Elite varieties have been identified for some spices but for medicinal plants this work has not been done yet.

2.4. Establish a national germplasm & seed bank for medicinal plants. Aggressively develop the seed material and make it available for cultivation. Provide subsidies for the cultivation of red listed plants.

2.5. India specific Good Agricultural Practices (GAPs), Good Harvesting Practices (GHPs) could be prepared by National Medicinal Plant Board (NMPB)

2.6. In-vitro pharmacology and analytical phyto-chemistry laboratories are very few in India and are crucial for standardization of natural products. A national long term project can give contracts to various laboratories to facilitate the standardization of

natural products. As the labs are very few, the ministry should work with some development bank such as EXIM bank to promote such laboratories in key areas backed up by long term work, which is a national priority.

2.7. There exists a need to create competence in the core areas of molecular pharmacology by updating the academic curriculum and upgrading the learning systems. Training on assay systems development, etc., has to be taken up by CSIR laboratories. Several assays that provide higher content information about the drug substance are becoming increasingly unaffordable as several IPR issues are involved. The subject being important, the country needs to achieve some self reliance and hence the national herbal mission should undertake this task.

2.8. In key states, Ayurvedic/medicinal plant herbarium should be set up to collect, maintain and supply upon request authentic specimens of medicinal plants/ parts in a systematic manner.

2.9. Various government bodies are conducting scores of studies on herbal drugs. The current requirements of international bodies do not accept dated study protocols and demand high standards. Urgent audit is required on all these studies and pursue only such projects which are designed to meet international standards.

2.10. NIPER or a national laboratory should undertake special training programmes to SMEs on phytochemical isolation, molecular pharmacology, analytical testing, etc.

2.11. Urgent initiative should be taken in training all such clinical investigators and scientists on the design of clinical trials that are acceptable by international regulatory agencies. The current skill set available in modern medicine should be rapidly used in our traditional systems

3. **Regulatory Issues**

3.1. A convenient system to register Indian medicinal plants such as Ayurvedic herbs is required. While about 8,000 plant species are said to be medicinal, the medicinal uses of about 1,800 plant species are described in Ayurved. Many are described in folklore and some are in use. However, such plants which are not officially Ayurvedic/Siddha/ or Unani can not obtain manufacturing license as there is no procedure to add new plants/folklore plants.

3.2. Many of the significant Indian plants do not find place in the list of importable herbs in many countries. For example TGA Australia does not recognize any of the Indian pharmacopoeias while it recognizes Pharmacopoeia of the PRC of China. US FDA/ MHRA of UK, MCC of South Africa, TGA of Australia etc., have their own list of positive drugs which are safe and effective for permitting imports. We do not have such an official list that clearly states the important Indian medicinal plants that are safe and effective with reliable documentation. An urgent need, therefore, exists to compile the required data to enlist a herb in importable lists in various countries and initiate the registration of these herbs. A concerted effort is needed and the success

has to be monitored. Where applicable they may be classified as dietary supplements and in select cases as drugs.

3.3. Pharmexcil should provide a national registration cell which can provide information about the prevailing global rules and regulations governing natural products.

3.4. A periodic quality audit for AYUSH products exported from India should be undertaken to assure quality of the products.

4. Excise Issues

4.1. 'The intention of use' of a particular substance should govern the classification of a substance as a drug/health food/food. For example ginger can be a food and in some doses becomes an Ayurvedic drug and in another dose and form becomes a beverage. This has to be clarified with excise department as one of the steps to promote herbal sector.

4.2. All herbal raw materials are treated alike at forest check points. There exists a case to treat all cultivated herbal raw material and herbs collected from waste lands with a different perspective. Restrictions should be eased where the collection is from sustainable parts like leaves, flowers, seeds, fruits etc., simplification of transit permit/legal procurement certificate for transportation of raw drugs is essential.

4.3. Forest departments should create a list of plants/ trees where the collection is from sustainable parts, and should encourage herbal collectors to undergo proper training. Such training can help improve the overall quality of herbal raw material and reducing wastage.

5. International Opportunity

The herbal products in demand in various countries have to be researched and suitability & availability of Indian herbals for export production should be assessed. Trends in exports of herbal medicines, classes of herbal products, etc. should be analysed to re-orient Indian production to the requirements of International demand. Similarly, formulations popular in various countries should also be identified for manufacture and export of the same. The exercise would open gates for several opportunities for India in Herbal exports. The exercise requires dedicated and extensive research by various stake holders and initiation may be done in this direction.

10. Non Tariff Barriers & International Co-operation

10.1 International Cooperation

In its bilateral and multilateral trade agreements in the future, India ought to pay greater attention to extracting concessions on services, allowing for Indian medical professionals to practice outside, thereby increasing awareness about Indian healthcare as well as popularizing Indian System of Medicine, etc. India is in the process of negotiating several such agreements. In order to give impetus to our pharmaceutical industry, these agreements need to articulate our concerns by addressing them as follows:

i. Partner countries may not include pharmaceuticals in their sensitive lists.

ii. Drug registration process in partner countries may be harmonized and should not become a Non-Tariff Barrier (NTB).

iii. NTBs such as sanitary and phyto-sanitary regimes may not be adopted or if adopted may be harmonised.

iv. A mutual pharmaceutical cooperation regime can be negotiated which can complement each other's capacities. Since United States adopts a market restrictive approach in respect to pharmaceutical exporting countries which do not have free trade agreements with United States, it may be a good idea to examine the likelihood of entering into an enabling agreement with the US which would negate this artificial barrier created by US

10.2 Technical Barriers to Trade

In the interest of safety, efficacy and affordable medicine to the general population every country in the world regulates pharmaceutical industry in their respective countries. The regulation is all pervasive from price controls to reimbursement of pharmaceutical expenses to the consumers through national health protection/insurance schemes to drug registration, market authorization, quality control, quality standards, imports & distribution, packaging & labelling, intellectual property and even mergers and acquisitions in some countries.

While the countries are free to impose such regulation in keeping with their sovereign status, some of the regulation is excessive and non-justifiable. Some of the technical barriers to trade in various major

pharmaceutical markets are briefly elaborated below which will illustrate the entry barriers being faced by Indian manufacturers and where government intervention is required.

10.2.1 Multiple Approvals by Various Drug Regulatory Authorities

The multiplicity of drug approval agencies in various countries such as US FDA, UK MHRA, the European Medicines Agency (EMEA), European Directorate for Quality Medicines (EDQM), Ministry of Health, Labor, and Welfare (MHLW), Japan, The World Health Organization (WHO), Therapeutics Goods Administration (TGA), Australia, MCC, South Africa, etc. has raised drug registration costs and site inspections costs. These regulatory agencies insist on pharmaceutical standards & quality procedures of their country, which often varies from country to country.

Many countries including, EU, USA, Canada, Japan, etc., also have concluded mutual recognition agreements with countries with equivalent levels of GMP and registration standards. These agreements are meant to assure the quality of drugs imported into country issuing market authorization through mutual acceptance of GMP inspection results and exchange of information on drugs distributed in the two countries. However, India is not signatory to many of these mutual recognition agreements hindering the exports of the country's exports.

Automatic Approvals for Indian Facilities Recognised by Countries with Mutual Recognition Agreements

For products manufactured in USA and Australia there is a mutual acceptance. However, the same US FDA approved product in India will still need a plant inspection by Australian authorities. As Australia accepts US facility in situated in & approved by US FDA with out any inspection the same should be extended to US approved facility in India in an auto mode. We may negotiate such mutual agreements. Further, we should take up a bilateral discussion to accept Indian facilities approved by US or EU or TGA or HPB Canada or MCA South Africa without further inspections by various countries in the ROW. For example, even Nigeria, Ghana, etc.; want to inspect our facilities although our facilities are already approved by US or EU, etc. There is a justification to inspect if such facilities are not approved by any eminent countries.

The documentation to register drugs is extremely detailed and often is very expensive to provide such dossiers such as DMFS or ANDAS, etc. The review procedures of such documentation are very stringent and do not permit any low cost approach. The complete process details, site plans and all intricate details are demanded and have to be provided. This not only costs lot of money but also provides a free access to knowledge to employees in such agencies which diffuses into their systems. India on the other hand offers very little or almost no such restrictions making it easy for foreign manufacturers to enter the country. Our documentation reviews, inspections, etc., are meant to enhance the access of importation. .

While retaining such a broad objective, we have an urgent need to enhance our entry standards and inspections, etc., to enhance the standards in country.

Legislation for Import Permissions Should be Strengthened

Indian regulation for drugs & pharmaceutical products for imports is very simple in comparison with many major pharmaceutical markets. There is a case for reviewing the same and to bring it in line with international standards for imports

10.2.2 Bioequivalence Studies for Generics in Local Populations – An Emerging Technical Barrier

Japan, Mexico and now Thailand, etc., want the bioequivalence to be studied in their local populations in their countries. A bio-equivalence study merely compares the drug levels as compared to the original drug in-vivo. There is no clinical efficacy evaluation. Indian exports will suffer extensively if this technical barrier is adopted in more countries. US, Canada, Europe, South Africa, Australia and various countries accept BE studies conducted in India as per International guidelines. As each additional BE study costs more than Rs.50lacs for each additional country, this new NTB can adversely effect the product exports.

Negotiating NTB of Local BE Studies

India should immediately negotiate with countries such as Japan, Thailand, Mexico, etc. to accept Indian bioequivalence studies conducted in BE centres accepted by US FDA, etc. Concerned countries can inspect the bioequivalence centers. If required, we should engage international experts on bioequivalence to make a case for our negotiations.

10.2.3 Drug Registration Fees

Countries in European Union charge exorbitant fees for granting drug registration and approvals. This is so even with countries such as Japan, Russia, South Africa, Australia, Singapore, etc. This is in sharp contrast with USA which does not charge any such fees for filing DMFs & ANDAs. While a few countries of Europe seek the fees after due examination of the applications, many countries require the payment of fees in advance.

A fee has to be paid for each strength and variation. In EU countries if the registered contents of the dossiers (or drug master files (DMF)) are changed known as 'variation', (for example sourcing of Active Pharmaceutical Ingredient from one approved manufacturer to another approved manufacturer of the same API, or indications or packaging, etc.) an application to change the DMF or a slight modification notification must be submitted. When an application to change of the DMF is submitted, the applicant

must also submit a partial change application for the MF. If the variations are significant, EU countries (as also USA) often require filing of new application for license altogether.

The fees for registration is as high as US$99,000 in Singapore and it is approximately US$2,00,000/- to obtain registration for all strengths of one product in 25 countries of European Union. The bio-equivalence studies required for these registrations are costly and range between Rs.30lakhs to Rs.150lacs.

Realigning Registration Fees for Formulations APIs and Intermediates on par with other countries

It is suggested that we may realign our drug registration fees in line with other countries and use those funds to beef up our foreign inspection systems, introduce stringent dossier review systems, etc.

10.2.4 Reference Standards

Many countries insist on innovator standards of their countries. This is to say that Japan accepts reference standard of innovator product registered in Japan, Brazil accepts reference standard of innovator product registered in Brazil and so on. This implies to register a generic molecule such as paracetomol in a country such as Japan or Brazil, we have to obtain reference standards of paracetamol of the innovator company registered in Japan or Brazil. Often this places additional difficulties on exporters to obtain reference standards of different countries.

Generally small companies find it difficult to obtain innovator drugs in various countries due to several difficulties.

Procurement of Reference Standards in Foreign Countries

Possibilities for Indian embassies to help the companies in procuring the reference standards for R&D work to promote the exports should be examined.

In addition to challenge of obtaining these, they have to be pre-approved by DCGI called as test license. The conceptual role of DCGI in permitting these licenses especially for drugs that are registered in the country may be re-examined.

Test licenses approval system for drugs that are already approved in India should be immediately dispensed with. Test licenses for drugs that are already approved by US FDA or UK MHRA or other acceptable countries by DCGI can be delegated to state FDA to simplify the system.

10.2.5 Requirement for Local Presence

Japan requires tie-up with a local manufacturer or distributor for registration as also clinical trials for bio-equivalence studies (from three batches) in Japan which turns to be very expensive . For example in USA, we can submit ANDAs or DMFS with out a local establishment or a local partner. We simply need an FDA agent located in USA.

Negotiating for Waiver of Mandatory Local Presence

While negotiating with countries, India should get a concession to avoid requirements of local presence such as local manufacturer/subsidiary/company for entering the market. A local resident may be appointed as FDA agent to safeguard their concerns.

10.2.6 Government Procurement

Bidding for government tenders (e.g. USA) in many countries requires the exporting country such as India to be signatory to WTO agreement on Government Procurement.

Participation in US Government Business

The US Government business runs into billions of dollars due to availability of contract opportunities under Veterans' Administration (VA) procurement and other similar programmes. India is not a party to agreement on government procurement. Therefore, this opportunity is not readily available to us. It is, however, necessary to examine approaches which could open this opportunity for us, *albeit* indirectly.

The U.S. continues to be an attractive market for Indian firms, despite the challenges of price erosion and inability to bid for government purchases. The U.S. is in the process of negotiating or has concluded Free Trade Agreements with several countries which are Pharmaceutical producers, e.g. Thailand, Morocco, Chile etc. These agreements stipulate IPR related provisions such as data exclusivity, which have the effect of prohibiting pharmaceutical exports from other countries such as India. These stipulations by U.S. in its FTAs with different countries may be going beyond TRIPS and obviously such FTAs have implications for export of generic medicines from countries like India. To illustrate this – under the India-Chile FTA, while Chile can export pharmaceuticals at preferential terms to India, it is likely that India may not be able to export pharmaceuticals to Chile on those terms, in view of IPR stipulations in the US-Chile FTA. This needs to be addressed urgently.

India should comprehensively analyse the re-distribution effect of the RTAs in favour of member countries in pharmaceutical sector and negotiate tariff reductions on tariff lines of pharmaceutical products to neutralise the advantage accruing to the participants of the regional group.

10.2.7 Counterfeit & Spurious Drugs

There are variations in the definitions of counterfeit & spurious drugs in various regulated markets resulting in seizure and award of punitive damages against Indian Exporters. Especially in European Union the definition covers even generic versions of innovator drugs with out authorization even if they meet quality standards and also trademarks and copyrights leading to monopolistic practices. Even exports of such drugs to a country where patents are not granted to them and fully legal are liable for seizure if such products touch European ports during transit.

Products from some of the Indian SMEs were reported to have been seized in various European ports. Mention needs to be made to a recent case during a recent international trade fair Indian manufacturers were arrested and had legal action initiated against them in a major European Union country for mentioning in publicity material of the manufacturer a product patented in that country though it was mentioned in publicity material that the product is offered only in a country not having IPR restrictions. The concerned country's IPR regulation holds even such mention also as a violation.

10.2.8 Drug Regulatory Information Availability

Information availability in African countries is a major problem as many of these countries provide them in their local languages. This holds true with many European, CIS, LAC, Asean and other countries also. In the absence of websites in English language, information on drug registration, registrations granted, markets, etc. is not freely available to Indian exporters.

10.2.9 Specific Non-Tariff Barriers in Various Countries and Regions

Some of the specific restrictive factors acting as trade barriers to various countries and regions are given below;

Most of Latin American Countries (LAC) do not provide clear cut guidelines for drug registration or at least these are not available in public domain imposing avoidable hurdles on the manufacturer exporters seeking entry into these countries. For example check list of quality & efficacy tests, documents is not available in most of the Latin American Countries barring Brazil. Indian exporters in the absence of these check lists come to be aware of many requirements after submission of dossiers resulting in queries and resubmissions. To take a specific example, the specifications for drug registrations such as shelf life, stability tests, etc. are not available in public domain. Similarly, clear cut timelines or 'clock stops' for registration processes is also not available with many Latin American countries. Colombia on the other

hand has clearer guidelines and also insists on cGMP inspection of the sites. The country also does not insist on cGMP inspection and accepts valid recent inspection and approval certificates issued by a few other countries such as US FDA.

In Commonwealth of Independent States (CIS) countries, the queries raised during the registration & approval process vary from reviewer to reviewer. The standards in these countries also vary and it takes practically as long as 2 years for drug registration in these countries. The testing procedures in these countries are also long. Batch tests are performed before acceptance of documents for approval and again batch test are performed after review of submitted documents. Drug registration fees are also high in these countries. Only Ukraine has site inspections for cGMP while many other CIS countries do not insist on the same.

Many African countries insist on labelling and indications on the products in local languages. Many of the West & North African countries, numbering around 20, which are former French colonies and having substantial presence of French manufacturers, insist on indications to be printed in French language. Further many African countries do not want to promote imports of pharmaceutical products that are manufactured domestically as a measure of protection to domestic manufacturers or a measure to save foreign exchange. This restricts the trade in these products in those countries.

Centralised Regulatory Support for Export Promotion

It is very expensive to undertake drug registration at firm level and the knowledge and skills are generally not available in many firms. There is a compelling case to set up a strong regulatory affairs support cell in Pharmexcil which provides consultancy on regulatory matters in respect to various countries.. Such a cooperative effort will help institutionalization of knowledge and hasten the export registration in several countries. A central knowledge base with respect to regulatory matters in each and every country that not only keeps track of all regulations but actually undertakes registration work for Indian firms can be a substantial milestone in the evolution of pharmaceutical industry. Further, this is only way SMEs can afford to penetrate foreign countries faster. Similarly, these countries should be sensitized to accept valid GMP inspection certificates issued by other countries.

10.2.10 European Regulation of 'REACH' - an Emerging Barrier

The recent promulgation of 'REACH' regulation by EU has very deep impact on Indian exports of drug intermediates in particular and chemicals in general to Europe. The regulation not only adds to the cost of Indian manufactures making them uncompetitive but also poses several non-tariff barriers. The pharmaceutical SMEs and traders in drug intermediates may find it difficult to access European markets.

Many other countries such as USA, Canada, Australia, etc., are also undertaking exercises to introduce similar legislation.

REACH Regulation

An exercise should be undertaken with the European authorities to iron out technical barriers to Indian exports posed by 'REACH' till satisfactory solutions are reached.

India should consider introducing similar legislation in India.

Government should also actively follow similar legislation being introduced by other countries to thwart the threat posed by them.

10.2.11 Miscellaneous Barriers

Many small countries insist on attestation of all test certificates, export documents by their diplomatic missions. For example exports to Guatemala would require attestation of manufacturing license, quality certificate, etc. by their diplomatic mission. Many of these small nations do not have diplomatic mission in India posing hurdles for Indian exporters.

11. Aligning Internal Regulation

11.1 Price Controls

Almost every country in the world controls or regulates pharmaceutical prices either directly or indirectly. While some countries negotiate the drug prices listed in the reimbursement schedules, a few other countries control through insurance mechanisms/formulary listing mechanisms, etc. Varieties of such techniques are used to control prices. For example, recently Germany has put a ceiling on expenditure that can be incurred on marketing and trade by pharmaceutical manufacturers effectively curbing excessive expenditures in drug promotion and excessive incentives to trade.

Due to the consolidation of distribution or due to increased collective bargaining of retailers & wholesalers, controlling margins passed on to the trade this is becoming essential to ensure that investments in R&D and quality by manufacturer take place and benefits are passed on to the consumers. Similarly, controlling marketing expenditures in generics should also be pursued to achieve the same objectives. Controlling based on cost incurred for production has become an obsolete method. The marked up prices may have no relation to wages paid in marketing/distribution/R&D and various costs incurred in sales, distribution, etc. Some of the countries of late are also insisting on reduction of sale price to consumers if the margins to marketing intermediaries are raised.

Allowing for Price Rises to Plough Back Investments into Quality

There is a case to look at the possibility of allowing companies to charge additional prices to fund their quality investments and research for DPCO products while fixing the overall marketing expenditure and trade discounts as percentage of sales for all existing products. In the absence of such mechanism, India may also end up in intense consolidation of drug trade which will cripple the manufacturers and finally end up with out investments in most essential activities required for future. The government can consider a policy of equating investments in quality assurance equipment and related personnel with R&D for the purpose of tax benefits. Such a mechanism will help avoidance of low investments in quality and help industry to reach global standards.

11.2 Quality and GMP Regulation

As of now, one of the major issues facing the Indian Pharmaceutical sector is that, it is considered to be one of the largest producers of spurious and counterfeit drugs in the world. The FDA has voiced its concern regarding the same as has the EMEA.[20] Though this is not likely to affect the large

[20] Sean Eric Smith, *Opening up to the World: India's Pharmaceutical Companies Prepare For 2005*, Working Paper, Asia/Pacific Research Centre, Institute For Int'l Studies (May 2000).

pharmaceutical companies by virtue of the FDA certifications these organizations obtain for their facilities as also due to their reputation, medium and small scale companies are likely to be hard hit by the same.

Indian prices for essential drugs are already amongst the lowest in the world. The unrealistically low domestic market prices may not be conducive to investments in quality and R&D. Quality and GMP come at a cost. Economies of scale minimises the cost escalation while pursuing quality policies.

Drug safety and drug quality can be assured in today's environment only at a significant cost. However, economies of scale can make the drugs affordable. For example, based on manufacturers from countries like India, Wal-Mart is able to give monthly supply of select drugs for just US$ 4 per month. This clearly dispels the fear of cost escalation while pursuing quality.

By raising standards on drug approvals by insisting on in-depth in-vitro studies and in-vivo bioequivalent studies, we can assure right medicines for the population. Further, such regulation will curtail the current practice of production of scores of products in a single unit with small volume sizes that does not permit economies of scale or adherence to high quality standards. Indirectly such a move will make manufacturers to choose products and go for large volumes of production. For example, one thousand manufacturing units producing 100 products each with a batch of 1 lack is far inferior to 1,000 units producing 10 products each with a batch of 10 lacs. Continuous process will avoid wastages in manufacturing, reduce changeover times and make the country cost competitive. Hence, the regulations should be constantly strengthened to promote continuous productions and economy of scales to make industry competitive and also afford stringent quality standards of today's pharmaceutical world.

Currently, under schedule M each unit should have certain manufacturing and quality equipment requirements. Often, the investments for quality will constitute a significant proportion as compared to investment on manufacturing. In order to successfully implement schedule M government has to consider feasibility of a legislation to have central quality labs which can support multiple manufacturing units located at various places. In addition such legislation can encourage consolidation of small-scale units as they become competitive and can focus on economies of scale.

If bioequivalence is made mandatory over a period for key drugs produced by any manufacturer whether approved by state FDA or central FDA, the investments to obtain or renew a license will increase. In natural selection process, different companies will focus on different drugs based on their strengths. For example, instead of 2,000 companies manufacturing 200 drugs and each having comparative disadvantage, each company will focus on a few drugs and endeavour for economies of scale. Economies of scale permit for genuine measurement of quality.

Ensuring Reliable Product Quality

Bioequivalence and demanding relevant data to prove bioequivalence for any changes in process or change of machineries or change of production sites can guarantee the drug quality. These two measures in addition to strict cGMP inspections will assure the drug quality and safety and are expected to dissuade producers with low commitment to quality.

This will go a long way in avoiding substandard products and guarding the image of the country. India has a convention of setting up minimum norms in the areas of banking, insurance, etc., as a safe guard measure to public. Even drug production is an important subject and certain minimum investments will go a long way in assuring drug safety and quality to public and avoiding production of spurious drugs.

Redefining Minimum Investments for Reliable Quality

Prescribing certain minimum investments in quality and manufacturing keeping in mind the current global regulatory standards will ensure that only quality players would be encouraged. Over a period of time, for certain prescribed products, bioequivalence should be made mandatory whether a product is approved by state or central authorities.

Over a period of time change controls should be rigorously prescribed like SUPAC guidelines of USA which will assure drug quality and safety and avoid unexpected production of spurious drugs.

Campaigning Against Spurious Drugs

States should constitute legal-cum-intelligence cells for carrying on campaign against spurious drugs. There should be separate legal Departments with State Licensing Authorities (SLAs) as well as Central Licensing Authorities to take care of the issue of spurious drugs. There is a requirement for regular inspections so that quality is maintained. However, as there is a lack of infrastructure 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 also a need to train staff i.e., regulatory personnel with advanced techniques both at Center and the state level.

11.3 Foreign Site Inspections

India imports several APIs, formulations from foreign sites. Foreign site inspection assures quality and will reduce the risk of poor quality drugs for general population. Most countries depend on rigorous inspections and rigorous data screening and evaluation to assure quality. Further, foreign inspections will create awareness and improve perception in addition to intense knowledge capture. Knowledge enhancement in public organisations flows to industry and the standards of country will enhance. Most

governments charge for all costs incurred in site inspections and India may also follow suit in charging such fees for foreign products.

Foreign Site Inspections & Stringent GMP Audits to Ensure Quality Imports

Foreign inspections to approve every site/unit/block that exports to India like any international regulatory agency should be made mandatory. In addition regular audits to ensure genuineness of compliance should take place. Also parity in fees charged for drug approvals in India for foreign drugs in with fees charged for approval of Indian drugs in those countries should be brought.

11.4 Orientation & Training of Personnel involved in Drug Regulation and control

As the drug regulations involved in research, manufacturing, storage etc are constantly evolving procedures are constantly evolving and being very complex, the officers involved in inspection of drug regulatory matters should be trained, rotated in foreign inspections and should have mandatory re accreditation of qualifications to assure continuous success of industry.

Continuous Training and Up gradation of Officers

A procedure for training and 'accreditation' on continuous basis should be evolved for officers involved in drug regulatory matters and such officers lacking accreditation may be moved to non regulatory matters.

11.5 Amendments to procedures

1. The procedures and inter departmental approvals for commercial imports, exports, test license materials, development quantity imports, etc., have to be reviewed and simplified while maintaining control.

2. In the context of economies of scale, producing a generic with several variations in processes or colours or shapes or brand names as per the formula or requirements of importers across several countries is, mandatory. Drugs & Cosmetics act could not conceive such issues of today and in general one license for one product in one brand name is given. Provisions in this regard in Drugs & Cosmetics Act need revision along with permissions to give consequent free sales certificates, Certificate of Pharmaceutical Products (CPP), etc.

Expeditious Process by ADC at Customs & Ports

The approvals given by state DCIs and central DCGI should be made online for quick verifications by ADCs at customs & ports. In the context of aggressive sourcing of business from global markets, India will have to undertake production of several products and combinations for export

purpose which has to be approved by central DCGI and some times by state DCIs as the law requires. Online availability of all approvals of state and central drug controllers should be enabled at customs or ports to enhance efficiencies at customs/ports.

3. At present many export procedures such as preparation of free sales certificate, certificate of origin, GSP certificates, NOC certificates, etc., are done manually requiring cost & time. These documents could also be made online or department attaché may be given to significant exporters to issue these documents.

Electronic Submissions & Approvals

Online submissions, approvals, clearances should be permitted at least for status holder export organizations with time bound mechanisms to create a very business friendly climate.

4. The definition of spurious drugs is wide and issues related have to be dealt separately. However, there are glaring differences between Indian regulations and international regulations. For example, bioequivalence for drugs is mandatory (other than exceptions) in many countries whether a drug is new or old or whether approved by center or state. Similarly, site variations, source variations, process variations, etc., demand good amount of study to prove equivalence and such data has to be submitted to the authorities in these countries for approval. These two measures are very crucial to assure drug quality. In addition, manufacturing processes, environment controls, GMP practices, etc., are also necessary which are somewhat lenient in developing countries as compared to developed countries. While there are several issues in the implementation of regulations of different countries which have to be studied, it is essential to realize that investments in quality are equally important like R&D. Motivating industry to invest in quality is a very important direction for the country. Ultimately, such investments in quality coupled with gradual rise of standards will eliminate the spurious drugs issue. The issue of spurious drugs has come up for debate in the last couple of years. Spurious drugs have been variously defined but broadly include, substandard drugs, altogether fake products, and drugs with misrepresentations on labels. Internationally in some countries even those drugs were considered spurious which are not registered in that country but have come into that country through land trade from contiguous countries for example in some of the African countries. Availability of substandard or misrepresented drugs has not been denied and needs to be dealt with in the most deterrent manner as it tarnishes the image of India as a potent source of inexpensive medicines. This category of offences at present attracts relatively light penalties and even the enforcement of law is deficient for a variety of reasons. The proposed amendments to Drugs and Cosmetics act which will bring in requisite deterrence to the law and expand the enforcement framework of the government are being very eagerly awaited for a fairly long time. It is reported that relevant amendments to the act are still in the process and the bill might take

some time to be tabled before the parliament. These amendments are urgently required to reassert the credibility of Indian Pharmaceutical industry and must be taken on top most priority. The government could even consider promulgation of ordnance in view of the urgency associated with the subject. Be that as it may, the reputation of Indian Pharmaceuticals has also come under acute stress due to campaigns attributed to large multinational corporations as apprehended by industry experts. Some perceive these campaigns as yet another instrument of battles which are being fought in the market place between the Indian generic manufacturers and large multinationals. It is of immediate necessity that India should launch awareness and information campaign through expert marketing agencies and its missions in countries of consequence. It would also be necessary to take measures which will fill up gaps in export procedures which might encourage trade in spurious drugs.

Equate investments in Quality with R&D to Rejuvenate Indian Manufacturing

Investments in quality should be eligible for weighted tax deduction like R&D. This is necessary to motivate industry for higher compliance standards assuring high drug safety and higher quality standards.

Creation of Special Wing for Foreign Site Inspections & Audits

Foreign site inspections and Export quality control should be assigned to a special wing. Ensuring that every import comes from high quality sources and as per documentation helps in a big way, as many small scale formulators do not have highly sophisticated instrumentation to fully verify import claims and may end up producing spurious drugs. Further such a wing should collect control samples at regular intervals from exporters and analyse for compliance. Outsourcing of such work to highly sophisticated labs with strict timelines for analysis and results will motivate drug inspectors to do result oriented work. In case of process deviations, the quality mechanisms could be addressed at the company. This will help control production of spurious drugs, if any.

Proposed amendments to the Drugs and Cosmetics Act which will introduce severe penalties against offences relating to production and trade of spurious medicines should be carried out.

Creation of Clear Regulation for Bio-Similar Products

India is becoming a major player in manufacture of bio-similar products for marketing in the EU, Canada and elsewhere. At present bio-similar products are being treated as new drugs on an ad-hoc basis since there are no regulations on bio-similars. Therefore, science based specific regulations should be developed for approval of bio-similar products by Ministry of Health and Drug Controller General of India.

The problems in respect of alleged exports of counterfeit / spurious drugs by India have been a major challenge to us. In this Report, at a few places various dimensions of this problem have been discussed and solutions suggested. It is important that India should launch a high visibility campaign to remove any impression of India being a major centre for production and export of spurious drugs. This would require dealing at several levels, namely,

(i) **A high visibility campaign to be launched around the theme of brand India involving lobbying groups, marketing agencies, Indian Missions and other expert groups in major markets.**

(ii) **Putting together process mechanism which would negate the possibility of exports of sub-standard or outright spurious drugs**

(iii) **Fighting diplomatically at various international and regional fora battles which tend to enlarge the scope of counterfeit drugs encompassing even genuinely manufactured pharmaceuticals.**

(iv) **Taking policy initiatives which would discourage manufacturing of sub-standard or mislabelled drugs. Suggestions for this have been given at various places in this Report.**

12. Key Recommendations

Following paragraphs summarise the key recommendations made in earlier sections,

I. Accelerating the Growth of Generic Pharmaceutical Industry

1. Building Portfolio for Untapped Highly Attractive Opportunities

Prioritised funding by institutions like EXIM Bank through Special Purpose Vehicles (SPVs) has to be pursued aggressively. Such SPVs shall contract product development work for excellent but high initial cost opportunities such as specialty generics, topicals, steroids, hormones, biopharmaceuticals, non infringing process based DMFs/formulations, ANDAs, etc. Obviously, such funding is not a loan stretching the balance sheets of companies nor an equity dilution in the current company. An agreed percentage of revenues from the SPV funded projects will go back to the funding bank towards the investment and Internal Rate of Return (IRR). Once the funding BANK recovers its investment and IRR, the ownership of the products will flow back to the company without complications. Public and private initiative on a mega scale in this area is essential for jumpstarting India's pharmaceutical industry into a higher orbit achieving quantum growth. (Short Term)

2. Engineer Alliances to Protect Strategic Interests of the Country

Alliance initiatives between domestic companies funded through a venture capital concept by Exim bank, etc., should be promoted. Prioritizing funds to promote internal M&A is necessary in creating large Indian companies to counter the increased bargaining power of consolidated buyers.

3. **Enhancing Pool of Trained Professionals**

The country has to facilitate Learning and Development vigorously through public initiatives in enlarging the pool of skilled population in the areas of:

- Law
- Regulatory affairs
- Knowledge of market environment at the global level
- Patent procedures & filing
- Non Infringing Processes -concepts & strategies

Government should facilitate L&D for pharmaceutical professionals to enhance the learning opportunity and available pool of talent. (Medium Term)

4. **Treat Investments in Quality on Par with R&D to Enhance Quality and Skilled Scientific Personnel**

Insisting on stringent cGMP (current GMP) and bioequivalent drugs for key drugs can turn the table in enhancing the skilled population. Only when organizations have a need for higher quality, employees in

such organizations will have incentive to learn, update and join the elite trained pool of scientific personnel. While it directly benefits in increasing the skilled population, it also benefits in assuring quality drugs to Indian population. This is also a progressive step in controlling spurious drugs. Considering investments for Quality Control equipment at par with R&D capital goods purchases is a crucial step in rejuvenating Indian quality environment. (Short Term)

5**. Reviving Indian Drug Intermediate Industry**

The energy and labour costs differential has virtually eroded. In the past intermediate industry migrated to China due to these reasons. India is emerging as a significant supplier of finished APIs and formulations to regulated markets and ROW. China can capture our market with the strength in intermediates if India does not pay attention to building intermediate industry. Every year, several new chemical entities loose patent protection and the corresponding opportunity for several intermediates and finished APIs emerge. Government should setup an expert panel to study the potential intermediates that can come back to Indian manufacturing arena. Genuine foreign site inspections, analysis of imported samples of every consignment, in-depth review of regulatory submissions will put Indian industry on par with imports at least in strategic intermediates. (Medium Term)

6. **Looking At Narcotics Formulations as an Important Opportunity and Not Just a Menace**

In view of the above, it is therefore necessary, to simplify the procedure and to capture the global narcotics business in certain classes of narcotics. The entire process of approvals from multiple agencies such as DCGI, INCB, Ministry of Finance, State Narcotics Boards, the quota systems and canalization should be relooked at for promoting export production. The genuine manufacturer exporters may be permitted to directly import narcotic substances based on risk profiling and past records doing away with GOAW & ministry of finance approvals.

The quota system should be done away for export production as it is difficult to assess import requirements one year ahead especially when the country desires to capture a bigger share.

Obtaining INCB permission for each consignment of the same material for same importer and by the same vendor for certain classes of narcotics is not present even in developed countries such as Europe where the regulation is very stringent and must be done away with.

Online submissions, approvals and clearances should be considered. (Short Term)

7. **Reviving Fermentation Capabilities of India**

As the cost disadvantage is disappearing between China and India in energy and labour, the country should relook at fermentation R&D, Lyophilised pharmaceuticals, etc., Soft funding for fermentation projects as a kick off to bring back select intermediate industry especially in biopharmaceuticals and certain recent fermentation based intermediates/ APIs may be considered. (Medium Term)

8. Attracting Talent to Chemistry, Biology and Law

An integrated postgraduate course in chemistry could be offered in NITs, IITs, NIPER, and leading universities at the 10+2 level. Most bright students prefer engineering streams. Pure science in local colleges has become an unattractive destination. While chemistry is fancied to some extent, biology has much less attraction. Integrated courses in biology could be introduced at leading institutes focusing on microbiology, biotechnology and pharmacy. The quality of education in some of the private institutions offering these courses requires in-depth examination.

Integrated courses in law and life sciences should be introduced in premier law schools and universities.

A legal frame-work should be developed for tapping and developing the student potential while employing them for project works. However, as industry is not willing to offer projects in view of confidentiality issues, the legal framework should provide for confidentiality agreements by students and professors of universities. The confidentiality agreement should carry particulars such as passport details, permanent address of the student, etc. to trace them in the event of violations of such confidentiality agreements. Further, government should also make it mandatory for University Professors to produce a minimum number of projects/research works each year. Patentable research should drive these Institutions and universities. Increments and promotions may be linked to the research output and industrially commercialisable projects undertaken by their students/ departments. Grants etc. could be linked to the requirements of projects in terms of equipments/ space rather than mere capacity expansion etc. (Medium Term)

9. Thrust in developing Economies

Neglecting less developed markets may prove unwise in medium term. We should develop customised promotional programmes for markets in Africa, CIS, South East Asia and Latin America more vigorously. Non tariff barriers are constantly mounting in various parts of world. Although these markets are less regulated, the regulatory requirements and aspirations are escalating. Many current exporters in various countries with compromised infrastructures will find uneconomical to reinvest in businesses paving way for growth of Indian Pharmaceutical industry with high quality investments in manufacturing.

One key barrier is cost of product registration and consequent follow up for our highly fragmented industry. We have to go out of box and facilitate a shared structure to provide skilled registration services for our fragmented industry to capture the skill set, minimise costs through economies of scale. This will provide a breather to SMEs who have already invested heavily in manufacturing and finding it difficult to economically register and reach various markets. Learning the skill set and regulatory compliance issues for each and every country across world are prohibitively expensive for a SME. However such a draw back can be easily overcome with a public initiative in providing such service. The skill set achieved can be available for multiple organisations. Further procuring RLDs (Reference Listed Drugs) or Innovator samples across world is a very expensive and time consuming process for a SME. A shared service set up can overcome this barrier**.** (Medium Term)

10. Shared Marketing Services

Where feasible, Pharmexcil can facilitate marketing co-operation in destination countries, wherein a common entity can market the products for its members at a small marketing fees while remitting the entire revenues to the respective exporting member companies. This will help the co-operative entity enjoy larger product portfolio, large capacity as a backbone, economies of scale in distribution and warehousing, etc. and minimise the overall investments in the marketing**.** (Medium Term)

11. Identifying Strategies to Participate In Regional Clusters

In each regional cluster in the global pharmaceutical trade there exists a country in each cluster which supports all the neighbouring countries. Currently India competes with these regional champions in exports to the countries in the cluster. Over a period of time as regional champions emerge our exports could dry up. Pharmexcil should organise a study with the objective of finding practical strategies in utilizing these regional strengths for the furthering of our exports**.** (Short Term)

12**. Anti-diversion Mechanism in case of exports against compulsory licensing**

Indian companies should be careful to have anti-diversion mechanisms in place i.e. mechanisms to ensure that the medicines are consumed in the market for which they have been manufactured (the market which has declared the national emergency) and are not re-exported, as this would tarnish their reputation irretrievably. Pharmexcil should initiate a system with exporters wherein it creates awareness and promotes compliance. (Short Term)

II. Enhancing India's R&D

13. Treatment of R&D Expenditure for Tax Purposes

Outsourcing done by approved R&D, for example bio-equivalence studies which are integral part of R&D should be considered for weighted deduction. (Short Term)

14. Permitting Commercial R&D Subsidiaries for Tax Exemption

Commercial R&D firms promoted by established firms as subsidiaries should be allowed for the purpose of tax holidays in pharmaceutical industry. (Short Term).

15. Focusing on Immediately Commercialisable technologies By Government Institutions

One or two Indian scientific institutions should work along with domestic firms to identify target products which can benefit from these new technologies and take up projects. A small percentage of costs should be shared by industry firms and the technology may be licensed by them with out bottlenecks. (Medium Term)

16. Banks should provide certain capital for taking up commercialisable R&D

R&D being revenue expenditure, certain new technologies are taking a back seat in corporates that are already struggling for profits. Competing countries are investing in new technologies like biocatalysts, etc. forging ahead of India. Banks should develop SPV concepts to fund these technologies. (Medium Term)

17. Encouraging Public Private Initiatives in R&D

Major impetus to R & D should be given through the creation of synergy between the industry and academia where the 'cluster' model of the United States could be adopted. This may be accomplished through policy initiatives which stimulate research partnerships between pharmaceutical industry and academic institutions / publicly funded R&D organisations. Encourage the mobility between personnel from R & D institutions and the private sector. (Long Term)

18. Intense scrutiny of patentability of research is needed for grant of funds.

Pharmaceutical Research and Development Support Fund may have to be increased in size and clearer policies governing its application could be helpful. Encouraging tripartite partnerships between corporates, lending banks and the R&D fund may bring in investment in desired direction and its better utilization.

Revenue generating and patentable research should be the focus in research. Ensuring some participation of private sector in each project helps in adherence to time schedules and weeds away unattractive projects. The current global recession is releasing several scientific personnel in western world. Proactive steps in bringing experts to India to lead our projects or help us as consultants can bridge the vast gap in drug discovery value chain. Procedural issues in Visas etc can be resolved for specialists building our national projects. (Long Term)

19. R&D Incubators to Promote Entrepreneurship and New Ventures

BOT (Build operate Transfer) model in the lines of public private partnership could be considered to create a conglomerate to have 20 to 25 workstation in each incubation cell in each incubator. Such incubators in all major science cities such as Hyderabad, Bangalore, Pune, Chennai, Chandigarh, etc. under the aegis of NIPER may be promoted. Common storage, air handling, water, effluent management, analytical support is part of infrastructure. Depending on the location a capital out lay of Rs.5- 10 Cr may be required to revolutionize this concept. (Medium Term)

20. Enhancing Availability of Clinical Investigators/Researchers

India should attract Indian scientists to set-up service centres in India and provide Venture Capital funds on some prioritization basis. Efforts should be made to coordinate with medical colleges and pharmacy colleges to enhance focus and seats in clinical pharmacology. A study may be initiated for examining the

opportunity to set up a discipline for clinical research or a special training to become clinical investigators. **(**Medium Term)

21. Enhancing Capacity for Clinical Trials, Animal Toxicity/BE centres

Standardised project reports on building service centers should be developed and current medical institutions and hospitals should be motivated to evaluate setting up of such infrastructure. (Medium Term)

Clinical trials, bioequivalence studies, various toxicity study centers contributing in drug discovery work could be unambiguously termed as R&D investment eligible for tax holidays and weighted deduction.

Drug discovery firms cannot do all work in house and they need to outsource some of work like testing, etc., to third parties. Such outsourcing portion by a government approved R&D facility should be considered for weighted deduction. In the absence of this, each firm has a miniature service center for its own purpose and the sector can not develop and skills required can not be institutionalized.

22. Government Body Should Facilitate Learning and Legislation with Respect to IRBs

A course familiarizing Institutional Review Boards (IRBs) could be designed and the information should be communicated to eminent eligible people retiring from various service sectors. By attracting them to understand the opportunity and familiarizing them with the subject, the country can enhance pool of available experts to help these boards. (Short Term)

23**. Service Tax Exemptions for Pharmaceutical R&D**

R&D services may be exempted from service tax for national priority sectors. Providing drugs for Indian citizens is a big priority for nation and this sector could be waived from the net. (Short Term**)**

24**. VC Funding for CROs to Promote Value Chain in Drug Discovery**

Prioritised Venture Capital based funding should be provided to set up large contract research organizations. (Medium Term)

III. Promoting Contract Manufacturing, Drug Discovery & Clinical Trials

25**. Investing in Key Links to Accelerate Outsourcing Business**

Government should promote capacity building in testing laboratories for stability studies, bioequivalence studies and third party analytical laboratories urgently through policy action, appropriate incentives and venture capital. Such facilities can be made available to SMEs at subsidised rates to reduce entry barriers and encourage competition from start-ups in drug discovery and other key growth segments. (Medium Term)

26**. Promoting SEZs to Accelerate Contract Manufacturing**

SEZs should be promoted consciously in the area of formulations and APIs to ensure that Indian industry compares at par with international locations. (Short Term)

27**. Exemption from Export Duties to SEZ Units**

Export duties applicable to exports should not be charged to SEZ purchases. (Medium Term)

28. Formulating Practical Norms for Pharmaceutical SEZs

Domestic sales up to a fixed percentage of capacity installed should be allowed for export oriented pharmaceutical units.

First year of profits should be considered for beginning the tax holiday period**.** (Short Term)

29. **Resolving Hurdles in Contract Manufacturing**

The Government should look at developing a practical and operable system, which should be adopted by contract manufacturers where in the goods come for processing without paying any duty and go back with out any duties except for the processing costs or value addition. The system should have compliance of Drugs and Cosmetics Act as such manufacturing requires lot of documentation meeting the regulatory requirements of various destination countries. Typically, the inputs come from a country and the output will have to go to several countries. Even in standard contract manufacturing, there are issues of free sale certificates, etc. hence there is a requirement for an interdepartmental meet to appreciate the issues involved and develop appropriate departmental notifications. (Short Term)

30. **Pharmexcil's Role in education on Intricate Issues in International Contracts**

In the interest of manufacturers, Pharmexcil should develop standardized agreements and caution on various clauses and their implications to the firm in the long term. A one time effort employing international experts will raise the standards of understanding in this regard. (Short Term)

31**. Intricacies in Negotiation of Contract Manufacturing**

Pharmexcil should organize learning module on contract manufacturing negotiations and help small and medium scale entrepreneurs appreciate the issues of short term and long term. There exists a case to evaluate whether company law provisions have to be amended to bring in exclusive licensing of substantial capacity on par with hiving-off substantial assets. (Short Term)

32. **Incentives to CRO**

The incentives mentioned in the draft National Pharmaceuticals Policy of 2006 such as exemption of service tax for direct investment in the field of clinical development and data management, exemption from import duty, improved regulatory infrastructure and some form of protection for undisclosed test data, etc., ought to be acted upon. (Short Term)

33. Simplifying approval procedures for Clinical Trials Export/Import Materials

Established/accredited CROs should be permitted to take one time clearance for import/export of clinical trial materials if the parties to the contract are the same avoiding repeated clearances from various agencies. Based on risk profiling approval from single agency should be considered as time element is most crucial in obtaining and executing of contracts.

Companies engaged in stability testing will have to test large number of samples and import duty on these consignments will severly impact the business. Analytical testing like stability testing etc are good opportunities despite our handicap of distance and transportation. Government should draft necessary legislation keeping the new dimensions and opportunities in the pharmaceutical business. Extensive decentralisation and online approvals are essential. Self approval facility should be given for established corporates based on some risk profiling and audits**.** (Short Term)

34**. Decentralisation of Approval System**

There is a need to promptly decentralize the approval system (e.g., State DCI approval) of T licenses for already approved drugs in India. Automatic approval may be given for new drugs for "invitro testing work'' or if the testing is not in humans (e.g., State DCI). The process of importation of blood samples for analysis has to be simplified. Risk profiling should be done and reputed clients and reputed service centers in India may be given exemptions with obligation to submit annual reports.

Such certificates should be available on line for substantial exporters or a drug control office employee empowered to sign such documents should be posted at corporates with huge requirement of procedural documents. (Short Term)

IV. Indian System of Medicines & AYUSH

35. Promoting AYUSH Education

Greater attention is required to AYUSH education as well as infrastructure in institutions imparting AYUSH education.

A possible way of facilitating exports could be to create a single window for clearances for companies wishing to export ASU products.

There is great potential for AYUSH to flourish regionally i.e., in South Asia where there is an existing culture of AYUSH, as well as South East Asia which also has had traditional medicines of various kinds historically. A great deal, however, depends on private initiative and business methods to create awareness and start marketing in these regions. Negotiations should open up regional cooperation in the

services sector with South Asian countries to allow AYUSH doctors practice across the countries in the region**.** (Medium Term)

36**. Extension of Concessions to AYUSH Products on par with Pharmaceutical Products**

The Foreign Trade Policy allows some concessions for pharmaceutical products but makes no mention of AYUSH products as a distinct category. Remedying this could have a beneficial effect on the industry, which requires assistance for large scale technical up gradation. Fiscal benefits granted to the industry for such up gradation, could also act as incentives to the industry. (Short Term)

37. Focus Product Scheme - Top 25 plants, their products and extracts; and Top 50 Ayurvedic formulations, should be identified for special thrust

37.1. Funds must be provided for compiling internationally acceptable Drug Master Files for these products and there must be a concerted push between various Ministries to ensure that these products are allowed market access in all countries.

37.2. The Vishesh Krishi Upaj Yojana (VKUY) should also include extracts as well as compounds isolated from the herbs so identified under the Focus product scheme.

37.3. These focus products should have a published information on minimum purchase price and minimum quantity for a minimum period of time to encourage reliable cultivation. Produce from both wild sources and cultivated land should be encouraged independently.

37.4. To achieve desired purity level at various micro units spread across the country may not be economically feasible. Hence these have to be bought at a gross level and routed to select central units for purification to bring them to the required quality standards. Processing zones, near important cultivation areas should be developed where the whole process of adding value to the raw medicinal plants takes place.

37.5. Ethanol availability to recognized Ayush industries producing these products should be on a fast track and assured basis.

37.6. These formulations should be given complete tax concession with respect to excise duty/ vat etc. when priced at a predetermined threshold cost of therapy per day at therapeutic doses and having therapeutic claims.

37.7. Identify & promote Agri Export Zones (AEZs) for these plants.

37.8. Encourage clinical trial work to establish efficacy/safety and process standardisation of various formulations. Government should conceptualise a project and approach established pharmaceutical companies or established R&D labs, to conduct necessary research for select Ayurvedic preparations especially analytical research.

37.9. Provide a meaningful financial assistance (for example Rs. 50 laks) as a grant if the product satisfies certain parameters such as:

37.1.1. Complies with guidelines on heavy metal/pesticide/mycotoxin/microbial residues

37.1.2. Efficacy is proven by 2 double blind controlled trials

37.1.3. Analytical/chromatographic methods have been developed which facilitate both qualitative and quantitative estimation of ingredients

37.1.4. Is from sustainably usable plant parts for at least 70% of ingredients.

37.1.5. At least 2 publications in reputed journals of pharmaceuticals on the product. (Medium Term)

38. **Creating National Resources in Herbals**

38.1. Schedule 1 of Drug & Cosmetics act lists 57 official Ayurvedic books. Many are out of print and these should be made available and digitized. List of Ayurvedic herbs of India as mentioned in these books should also be made available.

38.2. Compile a comprehensive national database on the available scientific information about safety efficacy phytochemistry and clinical data on each Indian medicinal plant. Create a national library of primary phytochemical reference standards and cost effective testing of herbal products.

38.3. Government should initiate specific research programs through state agricultural universities aimed at searching, identifying elite species/ varieties/ chemotypes of those medicinal plants whose quality assessment criteria have been standardized. Herbal extract/product manufacturers having access to high quality raw material (elite varieties) become very critical for maintaining economic viability/competitiveness in both domestic and international markets. Elite varieties have been identified for some spices but for medicinal plants this work has not been done yet.

38.4. Establish a national germplasm & seed bank for medicinal plants. Aggressively develop the seed material and make it available for cultivation. Provide subsidies for the cultivation of red listed plants.

38.5. India specific Good Agricultural Practices (GAPs), Good Harvesting Practices (GHPs) could be prepared by National Medicinal Plant Board (NMPB)

38.6. In-vitro pharmacology and analytical phyto-chemistry laboratories are very few in India and are crucial for standardization of natural products. A national long term project can give contracts to various laboratories to facilitate the standardization of natural products. As the labs are very few, the ministry should work with some development bank such as EXIM bank to promote such laboratories in key areas backed up by long term work, which is a national priority.

38.7. There exists a need to create competence in the core areas of molecular pharmacology by updating the academic curriculum and upgrading the learning systems. Training on assay systems development, etc., has to be taken up by CSIR laboratories. Several assays that provide higher content information about the drug substance are becoming increasingly unaffordable as several IPR issues are involved. The subject being important, the country needs to achieve some self reliance and hence the national herbal mission should undertake this task.

38.8. In key states, Ayurvedic/medicinal plant herbarium should be set up to collect, maintain and supply upon request authentic specimens of medicinal plants/ parts in a systematic manner.

38.9. Various government bodies are conducting scores of studies on herbal drugs. The current requirements of international bodies do not accept dated study protocols and demand high standards. Urgent audit is required on all these studies and pursue only such projects which are designed to meet international standards.

38.10. NIPER or a national laboratory should undertake special training programmes to SMEs on phytochemical isolation, molecular pharmacology, analytical testing, etc.

38.11. Pharmexcil or some government body should take urgent initiative in training all such clinical investigators and scientists on the design of clinical trials that are acceptable by international regulatory agencies. The current skill set available in modern medicine should be rapidly used in our traditional systems. (Medium Term)

39. **Regulatory Issues**

39.1. A convenient system to register Indian medicinal plants such as Ayurvedic herbs is required. While about 8,000 plant species are said to be medicinal, the medicinal uses of about 1,800 plant species are described in Ayurved. Many are described in folklore and some are in use. However, such plants which are not officially Ayurvedic/Siddha/ or Unani can not obtain manufacturing license as there is no procedure to add new plants/folklore plants.

39.2. Many of the significant Indian plants do not find place in the list of importable herbs in many countries. For example TGA Australia does not recognize any of the Indian pharmacopoeias while it recognizes Pharmacopoeia of the PRC of China. US FDA/ MHRA of UK, MCC of South Africa, TGA of Australia etc., have their own list of positive drugs which are safe and effective for permitting imports. We do not have such an official list that clearly states the important Indian medicinal plants that are safe and effective with reliable documentation. An urgent need, therefore, exists to compile the required data to enlist a herb in importable lists in various countries and initiate the registration of these herbs.

39.3. A concerted effort by the government is needed and the success has to be monitored. Where applicable they may be classified as dietary supplements and in select cases as drugs.

39.4. Indian Traditional medicine should be negotiated for exclusion from all sensitives lists under various bilateral and regional preferential trade agreements entered into by India.

39.5. Pharmexcil should provide a national registration cell which can provide information about the prevailing global rules and regulations governing natural products.

39.6. A periodic quality audit for AYUSH products exported from India should be undertaken to assure quality of the products. (Medium Term)

39.7. An export certification system for Ayush products in respect to heavy metals, pesticide residues, alfatoxins and other toxic materials should be put in place. To begin with this could be based on a self certification approach.

40. **Excise and forestry Issues**

40.1. 'The intention of use' of a particular substance should govern the classification of a substance as a drug/health food/food. For example ginger can be a food and in some doses becomes an Ayurvedic drug and in another dose and form becomes a beverage. This has to be clarified with excise department as one of the steps to promote herbal sector.

40.2. All herbal raw materials are treated alike at forest check points. There exists a case to treat all cultivated herbal raw material and herbs collected from waste lands with a different perspective. Restrictions should be eased where the collection is from sustainable parts like leaves, flowers, seeds, fruits etc., simplification of transit permit/legal procurement certificate for transportation of raw drugs is essential.

40.3. Forest departments should create a list of plants/ trees where the collection is from sustainable parts, and should encourage herbal collectors to undergo proper training. Such training can help improve the overall quality of herbal raw material and reducing wastage. (Medium Term)

41. **International Opportunity**

The herbal products in demand in various countries have to be researched and suitability & availability of Indian herbals for export production should be assessed. Trends in exports of herbal medicines, classes of herbal products, etc. should be analysed to re-orient Indian production to the requirements of International demand. Similarly, formulations popular in various countries should also be identified for manufacture and export of the same. The exercise would open gates for several opportunities for India in Herbal exports. The exercise requires dedicated and extensive research by various stake holders. (Medium Term)

V Non-Tariff Barriers & International Co-operation

42. **Automatic Approvals for Indian Facilities Recognised by Countries with Mutual Recognition Agreements**

For products manufactured in USA and Australia there is a mutual acceptance. However, the same US FDA approved product in India will still need a plant inspection by Australian authorities. As Australia accepts US facility with out any inspection the same should be extended to US approved facility in India in a auto mode. We may negotiate for such mutual agreements. Further, we should take up a bilateral discussion to accept Indian facilities approved by US or EU or TGA or HPB Canada or MCA South Africa without further inspections by various countries in the ROW. For example, even Nigeria, Ghana, etc.; want to inspect our facilities although our facilities are already approved by US or EU, etc. There is a justification to inspect if such facilities are not approved by any eminent countries. (Medium Term)

43. **Legislation for Import Permissions should be strengthened**

Indian regulation for drugs & pharmaceutical products for imports is very simple in comparison with many major pharmaceutical markets. There is a case for reviewing the same and to bring it in line with international standards for imports. (Short Term)

44. **Negotiating NTB of Local BE Studies**

India should immediately negotiate with countries such as Japan, Thailand, Mexico to accept Indian bioequivalence studies conducted in BE centres accepted by US FDA, etc. Concerned countries can inspect the bioequivalence centers. If required, we should engage international experts on bioequivalence to make a case for our negotiations. (Short Term)

45. Realigning Registration Fees for Formulations APIs and Intermediates on par with other countries

India may realign its drug registration fees in line with other countries and use those funds to beef up its foreign inspection systems, introduce stringent dossier review systems, etc.

As a bilateral point, study the feasibility of a reduced fee for registration of products on a mutual concession basis**.** (Medium Term)

46. **Negotiating for Waiver of Mandatory Local Presence**

While negotiating with countries, India should get a concession to avoid requirements of local presence such as local manufacturer/subsidiary/company for entering the market. A local resident may be appointed as FDA agent to safeguard their concerns. (Medium Term)

47. **Participation in US Government Business**

India should examine the ways whereby agreements that enable Indian manufacturers to supply/bid pharmaceuticals to Government contracts such as Veterans' Administration (VA) procurement, etc. could be negotiated. Such opportunity runs into billions of dollars. (Medium Term)

48. Negotiating for Resolution of Conflicting Definitions of Counterfeit Drugs

India should make all efforts to ensure that subterfuges to define 'counterfiet drugs' which will adversely affect Indian interests do not succeed.

India may also extend its co-operation in the fight against counterfeit drugs as this would improve the standards of local drugs as also enhance the image of the country**.** (Medium Term)

A programme to launch specific country based campaigns through our missions should be immediately undertaken with a view to spread awareness about Indian capacities among stakeholder groups and

particularly educate regulatory authorities in these countries about Indian pharmaceutical industry. Special visits of drug regulators from these countries to Indian industrial establishments and regulatory authorities should be organised on priority. (Short term)

49. **Centralised Regulatory Support for Export Promotion**

It is very expensive to undertake drug registration at firm level and the knowledge and skills are generally not available in many firms. There is a compelling case to set up a strong regulatory affairs support cell in Pharmexcil which registers drugs for various firms on a consulting basis in various countries. Such a cooperative effort will help institutionalization of knowledge and hasten the export registration in several countries. A central knowledge base with respect to regulatory matters in each and every country that not only keeps track of all regulations but actually undertakes registration work for Indian firms can be a substantial milestone in the evolution of pharmaceutical industry. Further, this is only way SMEs can afford to penetrate foreign countries faster. Similarly, these countries should be sensitized to accept valid GMP inspection certificates issued by other countries. (Short Term)

VI. Aligning Internal Regulation for surge in Exports

50**. Allowing for Price Rises to Plough Back Investments into Quality**

India should look at the possibility of allowing companies to charge additional prices to fund their quality investments and research for DPCO products while fixing the overall marketing expenditure and trade discounts as percentage of sales for all existing products. Absence of such mechanism may lead to intense consolidation of drug trade which will cripple the manufacturers and finally end up with out investments in most essential activities required for future. The government can consider a policy of equating investments in quality assurance equipment and related personnel with R&D for the purpose of tax benefits. Such a mechanism will help avoidance of low investments in quality and help industry to reach global standards. (Short Term)

51**. Ensuring Reliable Product Quality**

Bioequivalence and demanding relevant data to prove bioequivalence for any changes in process or change of machineries or change of production sites can guarantee the drug quality. These two measures in addition to strict cGMP inspections will assure the drug quality and safety and are expected to dissuade producers with low commitment to quality. (Medium Term)

52. Redefining Minimum Investments for Reliable Quality

Prescribing certain minimum investments in quality and manufacturing keeping in mind the current global regulatory standards will ensure that only quality players would be encouraged. Over a period of time, for certain prescribed products, bioequivalence should be made mandatory whether a product is approved by state or central authorities.

Over a period of time change controls should be rigorously prescribed like SUPAC guidelines of USA which will assure drug quality and safety and avoid unexpected production of spurious drugs**.** (Medium Term)

53**. Campaigning Against Spurious Drugs**

States should constitute legal-cum-intelligence cells for carrying on campaign against spurious drugs. There should be separate legal Departments with State Licensing Authorities (SLAs) as well as Central Licensing Authorities to take care of the issue of spurious drugs. There is a requirement for regular inspections so that quality is maintained. However, as there is a lack of infrastructure 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 also a need to train staff i.e., regulatory personnel with advanced techniques both at Center and the state level. (Medium Term)

54**. Foreign Site Inspections & Stringent GMP Audits to Ensure Quality Imports**

Foreign inspections to approve every site/unit/block that exports to India like any international regulatory agency should be made mandatory. In addition regular audits to ensure genuineness of compliance should take place. Also parity in fees charged for drug approvals in India for foreign drugs in with fees charged for approval of Indian drugs in those countries should be brought. (Short Term)

55. **Continuous Training and Up gradation of Officers**

A procedure for training and 'accreditation' on continuous basis should be evolved for officers involved in drug regulatory matters and such officers lacking accreditation may be moved to non regulatory matters. (Medium Term)

56**. Expeditious Process by ADC at Customs & Ports**

The approvals given by state DCIs and central DCGI should be made online for quick verifications by ADCs at customs & ports. In the context of aggressive sourcing of business from global markets, India will have to undertake production of several products and combinations for export purpose which has to be approved by central DCGI and some times by state DCIs as the law requires. Online availability of all approvals of state and central drug controllers should be enabled at customs or ports to enhance efficiencies at customs/ports. (Short Term)

57**. Electronic Submissions & Approvals**

Online submissions, approvals, clearances should be permitted at least for status holder export organizations with time bound mechanisms to create a very business friendly climate. (Short Term)

58**. Equate investments in Quality with R&D to Rejuvenate Indian Manufacturing**

Investments in quality should be eligible for weighted tax deduction like R&D. This is necessary to motivate industry for higher compliance standards assuring high drug safety and higher quality standards. (Short Term)

59. Creation of Special Wing for Foreign Site Inspections & Audits

Foreign site inspections and Export quality control should be assigned to a special wing. Ensuring that every import comes from high quality sources and as per documentation helps in a big way as many small scale formulators do not have highly sophisticated instrumentation to fully verify import claims and end up in producing spurious drugs. Further such a wing should collect control samples at regular intervals from exporters and analyse for compliance. Outsourcing of such work to highly sophisticated labs with strict timelines for analysis and results will motivate drug inspectors to do result oriented work. In case of process deviations, the quality mechanisms could be addressed at the company. This will help control production of spurious drugs, if any.

Proposed amendments to the Drugs and Cosmetics Act which will introduce severe penalties against offences relating to production and trade of spurious medicines should be carried out**.** (Short Term)

60**. Creation of Clear Regulation for Bio-Similar Products**

India is becoming a major player in manufacture of bio-similar products for marketing in the EU, Canada and elsewhere. At present bio-similar products are being treated as new drugs on an ad-hoc basis since there are no regulations on bio-similars. Therefore, science based specific regulations should be developed for approval of bio-similar products by Ministry of Health and Drug Controller General of India. (Short Term)

13. Other Issues & Recommendations

13.1 Ports

Complete digitisation requires to be undertaken for License registration by Customs at port/airports of India for improving turn-around times and reducing transactions costs. Pharmaceutical products should not be classified as general cargo and better facilities for storage (cold chain, etc.) need to be provided specially at the ports or airports which are important export centres for such products.

Improvement in availability of power and augmenting of facilities at major ports especially container terminals and bulk cargo terminals in order to reduce congestion is necessary.

Uniform charges for berthing in all Ports and EDI at all ports with message exchange stakeholders facilities ought to be implemented.

Highway connectivity from ports to the existing Chemical Zones and railway connectivity is absolutely necessary.

Pipeline transportation between ports & Chemical / Pharmaceutical Zones by Chemical / Pharmaceutical industry (using the existing pipeline infrastructure of public sector companies and other facilities on chargeable basis) ought to be encouraged.

13.2 Energy

The cost of power for the chemical/pharmaceutical industry in India is much higher as compared to China, Thailand, Indonesia and many other countries which render the country's industry less competitive in the international market. Irregularities in the delivery of power (voltage fluctuations, power cuts, etc.,) make it mandatory to set up alternate arrangements or have expensive captive power plants.

13.3 Transport

Under developed overland transport as well as port facilities mean that delivery schedules are often delayed, (viz., the time taken for delivery or the time taken for loading and unloading as well as the time required for obtaining clearance) leading to penalties as well as contributing to India's image as being somewhat unreliable in the international market.

13.4 Export Credit Guarantee Corporation (ECGC)

Export Credit Guarantee Cooperation needs to be made more effective particularly against the receipt of payments from CIS and East European countries. Department of Chemicals & Petrochemicals may need to address the problem.

13.5 Export Incentives

Duty Entitlement Pass Book (DEPB) should continue till an alternative scheme is in place.

13.6 Focus Market Scheme

Focus market scheme should be extended to all CIS countries, some of the LAC countries & Caribbean countries.

13.7 Service Tax / Excise

Levying of Service Tax for export services is not justified for exporters particularly for products having Brand Equity which are heavily advertised overseas and all services are rendered overseas. In all fairness all such services should be exempt from tax instead of the complicated drawback process. Moreover, the payment of Service Tax and subsequent claim of CENVAT or Drawback blocks the funds of the exporters and increases the transaction costs.

The requirement of producing a certificate of un-availed MODVAT duly countersigned by Central Excise Authorities for discharge of export obligation (which is required only against Value Based Licenses) seems to have no justification for Quantity Based Licenses. Arrangements for online applications seeking amendment/ extension of export obligation period/revalidation of licenses should be finalized.

13.8 DGFT Matters

1. The present input output norms for pharmaceutical products manufactured through non infringing processes are not captured in the current system. For export of bulk drugs, companies apply to DGFT for fixation of Input Output Norms for import of raw materials/ inputs under Duty Exemption Scheme. In such exercise, comparative data of other companies exporting same Product through conventional process is taken as one of the parameters/ basis for finalizing Norms of consumption of inputs. However, pharmaceutical products are patented through various production techniques & processes for reasons of patents and cost considerations. It has been noticed that the requirement of inputs by using Non Infringing patent processes are much higher than consumption norms available on record through conventional process. The present Foreign

Trade Policy (FTP) does not have any provision for considering such higher quantities of raw materials to avoid loss of revenue to exchequer.

A provision should be incorporated in the Foreign Trade Policy to consider fixation of separate SION for Non-infringing patented processes. DGFT may take up this issue for resolution.

2. Unrealised export receivable is another important issue which needs to be addressed. In order to penetrate various markets and expand the business in each market, entrepreneurs during their normal business process do take calculated risks. Under such scenario, APIs or formulations often get exported to scores of traders in addition to end users. Quite frequently all end users do not have dependable track records. Often ECGC covers costs more than the calculated bad debts. Due to variety of problems, certain portion of payments becomes unrealizable. In such cases, closure of licenses is a tedious process often taking several months. As the country advances, these problems multiply and there has to be some simplification of the system for closure of licenses. This will enable pharmaceutical manufacturers to focus on their core business more effectively.

   Voluntary disclosure of non-receipt and corresponding payment of duties availed along with specified interest to be paid by exporter to the concerned department must be considered for closing of licenses with automatic time limits.

14. Role of Pharmexcil in Facilitating Pharmaceutical Exports

14.1. Role of Pharmexcil

Pharmexcil at present is assigned the responsibility of facilitating export promotion in the pharmaceutical sector. Due to a variety of constraints pharmexcil is at present only scratching the surface and needs to do a lot. All this will be possible only through concerted efforts of the government and all segments of the industry. The following additional activities are suggested to be taken up by Pharmexcil:

A. Creation of Functional Desks

Functional desks should be created under Pharmexcil to assist industry and regulatory agencies in the following areas:

- **Legal** - Help Indian pharmaceutical organisations to understand intricacies in international contracts for international sale of goods, agency/distributor agreements, JVs, Technical tie-ups, legal environments of various countries, dos and don'ts with respect to obligations etc., Develop standard agreements/templates and keep in export council library, which can be used by members.
- **Marketing** - Help organisations to obtain international marketing knowledge. Develop information base on each country with respect to the structure of the market, environment, SWOT analysis, registration requirements, etc. Collect experiences on countries through active interface with industry and institutionalize the information.
- **Learning and Development (L&D)** - Providing L&D in marketing areas especially distribution, pricing, packaging, promotion, etc., knowledge about market environment in relevant countries to members.

B. Intellectual Property:

The IPR cell should take the following activities:

- **Intellectual Property Rights** - Help organisations in API process development and formulation development.
- Provide Learning & Development in IPR areas. Develop an information base of case laws related to IPR issues. Develop a learning module by experts for members to appreciate the intricacies in developing and defending non-infringing processes and invalidation of patents.
- Confidential evaluation of non-infringing processes and suggestions to build non-infringing processes for medium and small enterprises

Aggressive training programs in IPR with international experts to facilitate L&D are required in:

- Developing innovative process patents
- Drafting intelligent patents
- Training people in international patent laws and regulatory affairs laws

- Analyzing Legal case studies, etc.

C. Regulatory Research Desk

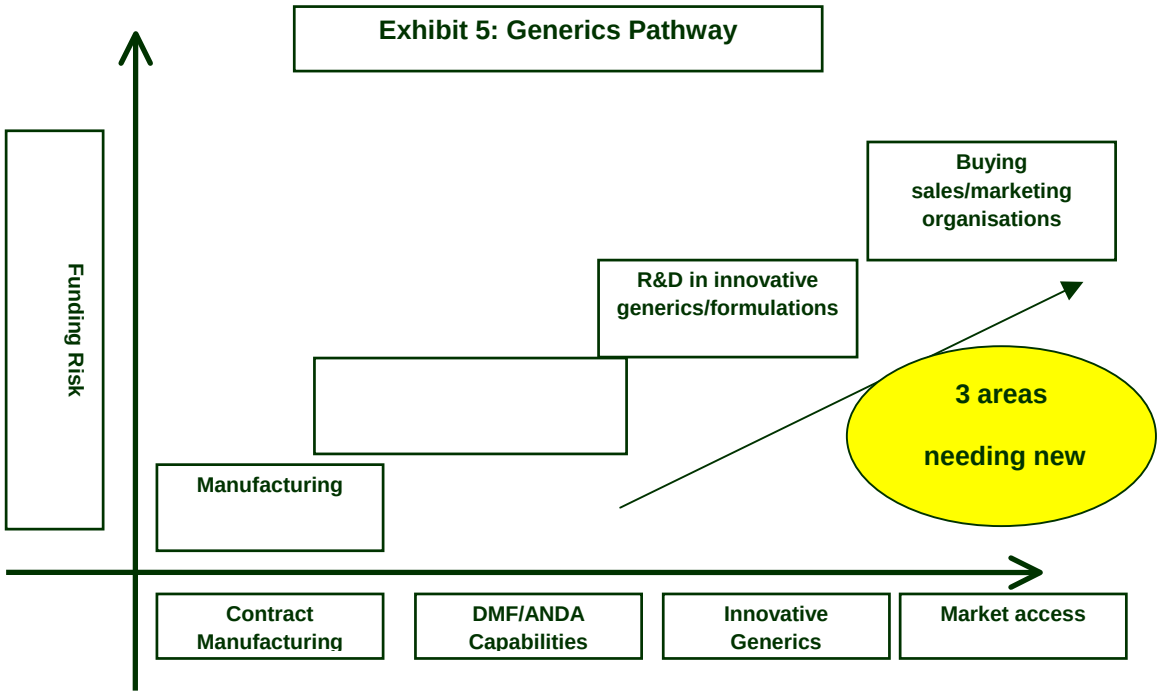
The role of the regulatory research desk should encompass:

a. Helping organisations in understanding regulatory procedures of various countries.
b. Developing useful information base on regulatory requirements, guidelines, and facilitate learning modules to understand the process of registration and understanding intricate issues involved in drug registrations.

E. Advisory Services Centre

- Providing guidance and inputs to financial institutions with respect to R&D. The main function is to encourage venture capital based funding in the areas of DMFs/ANDAs/innovative formulations/NCE building blocks such as contract research hubs; large testing centres, bioequivalence centres, data management centres on a risk and reward-sharing basis and patent filing fund which gives partial funding on profit sharing basis. Exim bank along with export promotion council can work on these strategies. (Exhibit 5 for Key areas requiring a framework).

Exhibit 5: Generics Pathway



The above cells, desks may also develop information databases in the following key areas:

a. Legal information base with standard templates to help members
b. Marketing information base with good information on various countries, market potential, marketing environment, etc.
c. IPR information base

d. Regulatory information base with good collection of all regulatory guidelines for various product classes, facilities in various countries.

Appendix – I

List of Indian Companies having Type-II (Active) DMF filing

Table : 25 List of Indian Companies having Type-II (Active) DMF filing

DMF HOLDER	LOCATION	NO. OF DMF
ALCHYMARS ICM SM PRIVATE LTD	TAMIL NADU, INDIA.	1
ALCON BIOSCIENCES PVT LTD	GUJARAT, INDIA.	1
ALEMBIC LIMITED (API DIVISION)	GUJARAT, INDIA	22
ALKALI METALS LTD	HYDERABAD, INDIA.	1
ALKALOIDS CORP	ANDHRA PRADESH, INDIA.	1
ALKEM LABORATORIES LTD	GUJARAT STATE, INDIA	1
ALPEX INTERNATIONAL PVT LTD	ANDHRA PRADESH, INDIA.	3
AMOLI ORGANICS PVT LTD	GUJARAT, INDIA	2
ANDHRA SUGARS LTD	ANDHRA PRADESH, INDIA.	2
ANJAN DRUG PVT LTD	TAMIL NADU INDIA	1
ANTIBIOTICOS SPA	CHENNAI, INDIA.	1
ANUH PHARMA LTD	MAHARASHTRA, INDIA	2
APICORE LLC	GUJARAT, INDIA FOR APICORE LLC	1
APOTEX PHARMACHEM INC	ANDHRA PRADESH INDIA	3
APOTEX PHARMACHEM INC	GUJARAT, INDIA.	2
APOTEX PHARMACHEM INC	BANGALORE, INDIA	5
ARCH PHARMALABS LTD	MAHARASHTRA, INDIA.	1
ARCH PHARMALABS LTD	HYDERABAD, INDIA.	4
ARTEMIS BIOTECH	HYDERABAD, INDIA.	1
ASENCE PHARMA PVT LTD	GUJARAT, INDIA	1
ASIAN HERBEX LTD	ANDHRA PRADESH, INDIA	1
AURO LABORATORIES LTD	MAHARASHTRA INDIA	1
AUROBINDO PHARMA LTD	ANDHRA PRADESH, INDIA.	119
AVENTIS PHARMA DEUTSCHLAND GMBH	GUJARAT, INDIA	1
AVON ORGANICS LTD	MAHARASHTRA, INDIA.	3
BASIC PHARMA LIFE SCIENCE PVT LTD	GUJARAT, INDIA.	3
BELCHER PHARMACEUTICALS INC	MAHARASHTRA, INDIA.	1
BENZOCHEM LIFESCIENCES PVT LTD	BOISAR, INDIA	6
BIOCON LTD	BANGALORE, INDIA.	16
CADILA HEALTHCARDE LIMITED	PADRA (GUJARAT), INDIA	61
CADILA PHARMACEUTICALS LTD	GUJARAT, INDIA.	28
CALYX CHEMICALS & PHARMACEUTICALS LIMITED	MAHARASHTRA INDIA	6
CENTAUR CHEMICALS PVT LTD	MAHARASHTRA, INDIA.	2
CIPLA LTD	MAHARASHTRA, INDIA	115
CIPLA LTD	BANGALORE, INDIA.	
CIPLA LTD	BOMBAY, INDIA.	
CIPLA LTD	MAHARASHTRA, BANGALORE, MUMBAI AND VERNA GOA, INDIA.	
CIPLA LTD	KURKUMBH, INDIA.	
CIPLA LTD	KURKUMBH, BANGALORE, PATALGANGA, VIKHROLI, INDIA	
CIPLA LTD	RAIGAD, INDIA.	
CONCORD BIOTECH LIMITED	AHMEDABAD, INDIA.	5
COVALENT LABORATORIES PRIVATE LTD	ANDHRA PRADESH, INDIA	1
CTX LIFE SCIENCES PVT LTD	GUJARAT, INDIA	3
DABUR INDIA LTD	NADIA WEST BENGAL INDIA	9
DISHMAN PHARMACEUTICALS AND CHEMICAL PVT LTD	AHMEDABAD, INDIA.	4
DIVIS LABORATORIES LIMITED	ANDHRA PRADESH INDIA	33

DOCTOR REDDYS LABORATORIES LTD	ANDHRA PRADESH, INDIA.	123
DOCTORS ORGANIC CHEMICALS LTD	ANDHRA PRADESH, INDIA.	1
DOSHION LIMITED	GUJARAT, INDIA.	3
DSM ANTI-INFECTIVES BV	HARYANA, INDIA	2
EMCURE PHARMACEUTICALS LTD	MAHARASHTRA INDIA	1
EMCURE PHARMACEUTICALS LTD	TAMILNADU, INDIA.	3
EMMELLEN BIOTECH PHARMACEUTICALS LTD	MAHARASHTRA, INDIA	3
ENALTEC LABS PVT LTD	MAHARASHTRA, INDIA	1
FDC LIMITED	MAHARASHTRA, INDIA	11
FDC PRIVATE LTD	ROHA, INDIA	1
FERMION OY	HYDERABAD INDIA	1
FLEMING LABORATORIES (INDIA)	ANDHRA PRADESH INDIA	2
GENESEN LABS LTD	MUMBAI, INDIA	2
GLAND PHARMA LTD	HYDERABAD INDIA	2
GLAND PHARMA LTD	ANDHRA PRADESH, INDIA	1
GLENMARK GENERICS LIMITED	GUJARAT, INDIA.	30
GLOCHEM INDUSTRIES LTD	ANDHRA PRADESH, INDIA.	5
GRANULES INDIA LIMITED	MEDAK INDIA	13
GUFIC BIOSCIENCES LTD	GUJARAT STATE, INDIA	4
GUFIC BIOSCIENCES LTD	MUMBAI, INDIA.	1
HALCYON LABS PRIVATE LTD	GUJARAT INDIA	4
HARIKA DRUGS PRIVATE LTD	ANDHRA PRADESH, INDIA	3
HARMAN FINOCHEM LIMITED	MAHARASHTRA INDIA	8
HETERO DRUGS LIMITED	ANDHRA PRADESH, INDIA	49
HIKAL LTD	BANGALORE, INDIA.	8
HINDUSTAN PHOSPHATES PVT LTD	INDORE (M.P.), INDIA.	1
IND SWIFT LABORATORIES LIMITED	PUNJAB INDIA	12
INDOCO REMEDIES LIMITED	RAIGAD DISTRICT, INDIA	2
INOGENT LABORATORIES PRIVATE LIMITED	HYDERABAD INDIA	1
INVENTAA CHEMICALS LIMITED	KRISHNA DISTRICT, INDIA.	1
IPCA LABORATORIES LTD	MAHARASHTRA, INDIA.	42
IPCA LABORATORIES LTD	INDORE, INDIA	
JAGSONPAL PHARMACEUTICALS LTD	FARIDABAD, INDIA.	1
JUBILANT OGANOSYS LTD	KARNATAKA, INDIA.	26
KESHAVA ORGANICS PVT LTD	MAHARASHTRA, INDIA	3
KREBS BIOCHEMICALS AND INDUSTRIES LTD	ANDHRA PRADESH, INDIA.	6
KUMAR ORGANIC PRODUCTS LIMITED	BANGALORE, INDIA.	1
LUPIN CHEMICALS LTD	MAHARASHTRA, INDIA.	72
LUPIN LABORATORIES LTD	ANKLESHWAR, INDIA	
LUPIN LABORATORIES LTD	MADHYA PRADESH, INDIA	
LUPIN LABORATORIES LTD	BOMBAY, INDIA	
MACLEODS PHARMACEUTICALS LIMITED	GUJARAT, INDIA	2
MALLADI DRUGS AND PHARMACEUTICALS LTD	TAMIL NADU INDIA	8
MARKSANS PHARMA LIMITED	PUNE INDIA	1
MATRIX LABORATORIES LIMITED	ANDHRA PRADESH, INDIA	
MEGAFINE PHARMA (P) LTD	GUJARAT INDIA	2
MENLA TIBETAN MEDICAL INSTITUTE	DHARAMSALA, INDIA	1
MOREPEN LABORATORIES LIMITED	HIMACHAL PRADESH, INDIA.	6
MSN LABORATORIES LIMITED	ANDHRA PRADESH, INDIA	13
MYLAN DEVELOPMENT CENTRE PVT LTD	MAHARASHTRA, INDIA.	1
N S CHEMICALS	MAHARASHTRA, INDIA.	1
NAKODA CHEMICALS LIMITED	ANDHRA PRADESH INDIA	1
NATCO PHARMA LIMITED	ANDHRA PRADESH, INDIA.	22
NAVINTA LLC	ANDHRA PRADESH INDIA	6
NAVINTA LLC	MAHARASHTRA,	1
NECTAR LIFESCIENCES LTD	PUNJAB, INDIA.	2
NEULAND LABORATORIES LTD	ANDHRA PRADESH, INDIA.	
NICHOLAS PIRAMAL INDIA LIMITED	ANDHRA PRADESH INDIA	8
NOVARTIS ENTERPRISES LTD	MAHARASHTRA, INDIA	2
NOVARTIS ENTERPRISES LTD	KERALA, INDIA.	1
NOVUS FINE CHEMICALS LLC	TAMIL NADU, INDIA.	1
OMEGAPHARMA PHARMACEUTICALS LTD	GUJARAT, INDIA	
ORCHID CHEMICALS AND PHARMACEUTICALS LTD	CHENNAI INDIA	53
ORCHID CHEMICALS AND PHARMACEUTICALS LTD	MAHARASHTRA, INDIA.	
ORCHID CHEMICALS AND PHARMACEUTICALS LTD	KANCHEEPURAM DISTRICT, INDIA.	
PARABOLIC DRUGS LTD	HARYANA, INDIA.	1
PARABOLIC DRUGS LTD	PUNJAB, INDIA	3
PEARL ORGANICS LTD	MAHARASHTRA, INDIA.	5
PHARMAZELL GMBH & CO KG	CHENNAI, INDIA	1

POSH CHEMICALS PRIVATE LIMITED	HYDERABAD INDIA	4
R L FINE CHEM	KARNATAKA, INDIA.	3
RA CHEM PHARMA LTD	ANDHRA PRADESH, INDIA	2
RELIANCE CELLULOSE PRODUCTS LTD	INDIA	1
RELIANCE INDUSTRIES LTD	GUJARAT, INDIA	1
RESOLUTION CHEMICALS LTD	ANDHRA PRADESH, INDIA	1
RIOCARE (I) PVT LTD	MAHARASHTRA, INDIA.	4
RPG LIFE SCIENCES LTD	MUMBAI, INDIA	2
S A PHARMACHEM PVT LTD	DADRA & NAGAR HAVELI, INDIA	1
S M HERBALS PVT LTD	RAJASTHAN INDIA	1
SAI ADVANTIUM PHARMA LIMITED	HYDERABAD INDIA	3
SAI ADVANTIUM PHARMA LTD	KARNATAKA, INDIA	1
SAI LIFE SCIENCES LIMITED	ANDHRA PRADESH INDIA	1
SAI PHYTOCEUTICALS PVT LTD	MADHYA PRADESH INDIA	6
SANDOZ PRIVATE LIMITED	MAHARASHTRA INDIA	6
SANMAR SPECIALITY CHEMICALS LIMITED	TAMIL NADU INDIA	3
SANOFI AVENTIS DEUTSCHLAND GMBH	GUJARAT INDIA	1
SARACA LABORATORIES LIMITED	HYDERABAD INDIA	2
SHASUN CHEMICALS AND DRUGS LTD	CUDDALORE, INDIA.	14
SHASUN CHEMICALS AND DRUGS LTD	PONDICHERRY, INDIA.	5
SIBRA PHARMACEUTICALS LTD (AN ARCH ENTERPRISE)	ANDHRA PRADESH, INDIA	4
SIGACHI CHLORO CHEMICALS PVT LTD	ANDHRA PRADESH, INDIA	1
SMRUTHI ORGANICS LTD	MAHARASHTRA, INDIA	4
SMS PHARMACEUTICALS LTD	ANDHRA PRADESH, INDIA.	11
SOHAN HEALTHCARE PVT LTD	PUNE, INDIA	1
SRI KRISHNA DRUGS LTD	A.P., INDIA.	5
SUN PHARMACEUTICAL INDUSTRIES LTD	GUJARAT INDIA	66
SUN PHARMACEUTICAL INDUSTRIES LTD	MAHARASHTRA INDIA	
SUVEN LIFE SCIENCES LIMITED	ANDHRA PRADESH INDIA	8
SYMBIOTEC PHARMALAB LIMITED	INDORE, INDIA.	4
SYMED LABS LTD	ANDHRA PRADESH, INDIA	6
SYNTHOKEM	HYDERABAD, ANDHRA PRADESH, INDIA	2
THERMAX LTD CHEMICAL DIV	MAHARASHTRA, INDIA	2
TONIRA PHARMA LTD	GUJARAT, INDIA.	3
TORRENT PHARMACEUTICALS LIMITED	GUJARAT INDIA	10
UNICHEM LABORATORIES LTD	RAIGAD, INDIA.	10
UNICHEM LABORATORIES LTD	DHAR (M.P.), INDIA	3
UNIMARK REMEDIES LIMITED	GUJARAT, INDIA	11
UNIQUE CHEMICALS	GUJARAT, INDIA.	6
USV LTD	MAHARASHTRA INDIA	21
VASUDHA PHARMA CHEM LTD	HYDERABAD, INDIA.	3
VENKAT PHARMA LTD	ANDHRA PRADESH, INDIA.	2
VIRCHOW LABORATORIES LIMITED	HYDERABAD, INDIA	1
VITALIFE LABORATORIES (A DIV OF ARCH PHARMALABS LTD)	HARYANA INDIA	5
VIVIMED LABS LTD	KARNATAKA, INDIA.	1
WANBURY LIMITED	MAHARASHTRA INDIA	6
WANBURY LTD	ANDHRA PRADESH INDIA	15
WATSON PHARMA PRIVATE LTD	MAHARASHTRA INDIA	16
WOCKHARDT LIMITED	GUJARAT INDIA	42
WOCKHARDT LTD	MAHARASHTRA STATE, INDIA.	
ZACH SYSTEM S P A	TAMIL NADU , INDIA	1
ZANDU CHEMICALS LTD	GUJARAT, INDIA	2
AARDEE EXTRUSIONS (INDIA) PV LTD	GUJARAT, INDIA	1

ACTAVIS PHARMA MANUFACTURING PRIVATE LTD	TAMIL NADU, INDIA	2
ACTAVIS PHARMA MANUFACTURING PRIVATE LTD	KANCHIPURAM, INDIA.	4
AKSHAT PHARMA PRIVATE LIMITED	ANDHRA PRADESH, INDIA.	1
ALCHEM INTERNATIONAL LTD	HARYANA, INDIA.	1
ALCHEM INTERNATIONAL LTD	NEW DELHI, INDIA.	1
RANBAXY PHARMACEUTICALS	MADHYA PRADESH, INDIA	93
RANBAXY LABORATORIES LTD	PUNJAB, INDIA.	

Appendix – II

Major Pharmaceutical Projects in India

Table 26: Top 15 Pharmaceutical Projects in India

Sl. No.	Company Name	Project Name	Project Status	Project Cost (Rs. Crore)
1	Zydus Infrastructure Ltd.	Pharma S E Z Project	Under Implementation	1,000
2	Biocon Ltd.	Biopharma (Insulin) Project	Announcement	700
3	Wockhardt Ltd.	Shendre Pharmaceuticals S E Z Project	Under Implementation	700
4	Meditab Specialities Pvt. Ltd.	Keri Pharma S E Z Project	Under Implementation	650
5	Dishman Infrastructure Ltd.	Pharma S E Z Project	Under Implementation	600
6	Biocon Ltd.	'Statin' Drug Capacity Expansion Project	Under Implementation	500
7	Eisai Pharmaceuticals India Pvt. Ltd.	Vizag Pharma (Api) - R & D Centre Project	Announcement	500
8	Tamilnadu Industrial Devp. Corpn. Ltd.	Biogenomics & Bioinformatics Project	Under Implementation	450
9	Andhra Pradesh Indl. Infrastructure Corpn. Ltd.	Indira Gandhi Centre For Advanced Research Centre On Livestock Project	Announcement	400
10	Cipla Ltd.	Goa Drug Formulation Expansion Project	Announcement	400
11	Government Of Andhra Pradesh	Jadcherla Vaccine Centre Project	Announcement	400

Source: CMIE database 'Capex' (as on 30th June, 2008)

Appendix – III

R&D Efforts in India

In the medium term the Indian pharmaceutical industry cannot generate adequate revenues to do significant basic R&D. Research in known leads or analogues has produced some success and the country is at a very nascent stage in drug discovery.

In the coming years, India needs own products. It has to synergise government institutions, Universities & industry to develop own drugs. Such effort needs large balance sheet for companies. Progress in exports and public private initiatives are therefore mandatory. Governments across world take very serious and at times ruthless initiatives in pharmaceutical matters by forging linkages of industry, academia and scientific & financial institutions either to guard the current eminence or to protect the health needs of their citizens.

There is a need for regulatory reform in India to encourage leading global players to continue and accelerate the outsourcing of their R&D activities-beginning with discovery research-to the subcontinent. This is particularly urgent in the face of the strong competition from China, where the government has been particularly proactive in encouraging foreign investments in pharmaceuticals and biotechnology.

An OECD report on the nature of research funding in India has shown that there are a number of organisations which are engaged in research on biotechnology in India, including, the Department of Scientific and Industrial Research (DSIR), the Department of Science and Technology (DST), the Department of Biotechnology (DBT), the Indian Council of Agricultural Research (ICAR) and the Indian Council of Medical Research (ICMR) that have programmes supporting biotechnology and each of them has growing allocations for biotechnology.[21] However apart from DBT none of these have specific allocations earmarked for areas of research such as biotechnology, etc.

This means that in the realm of pharmaceutical research generally and more particularly in the realm of biotechnology based research, there is a great likelihood that research funding is being duplicated i.e. not being used to optimal effect. Venture capital has emerged as a major source for funding, but this needs to be encouraged more.

[21] Sachin Chaturvedi, "Dynamics of Biotechnology Research and Industry in India: Statistics, Perspectives and Key Policy Issues", OECD Document No. DSTI/DOC (2005)6, available at http://www.oecd.org/dataoecd/43/35/34947073.pdf.

Appendix - IV

Status of Patents and Intellectual Property Rights

India's new product patent regime has emerged as a consequence of its being a signatory to the TRIPS agreement. India's parliament approved the *Patents (Amendment) Act* 2005, bringing in a system of product patents backdated to January 1, 2005. The new regime protects only products arriving on the market after January 1, 1995, abolishing the previous process patent system established by the 1970 *Patent Act*.

(i) The Patent Act and Introduction of product patents

Globalization and the WTO put India under an obligation to amend the Patents Act in compliance with the provisions of TRIPS.[22] According to TRIPS, the developing countries (including India) had time until January 1, 2005, to enact domestic legislation to conform with the agreement, whereas the LDCs were given time until 2016. And since the Indian patent regime did not provide product patents for pharmaceuticals and agro-based products, it became obligatory to provide for a 'mail box' facility for filing patent claims to protect these products with effect from 1st January, 1995. Similarly, those 'mail box' patent applications that satisfied certain conditions were entitled to receive exclusive marketing rights for five years. The date of application of TRIPS provisions, other than product patents, was January 1, 2000.[23] The amendment came into force in 1999 retrospective from 1995. In 2002 India had to amend the Patents Act again to meet with the second set of obligations, which had to be effected from January 1, 2000. This amendment provided, among other things, for a 20-year term for the patent and for the reversal of the burden of proof. The latest amendment of the Patents Act came into force on January 1, 2005, incorporating the provisions for granting product patent in all fields of technology including chemicals, food, drugs & agrochemicals.

In order to protect the interest of Indian industry, including the pharmaceutical industry, full transition period of ten years available under the TRIPS Agreement was utilized. In the amendment, a provision was made that in respect of applications for drugs and medicines filed before 1.1.2005, the rights of patentee shall accrue only from the date of grant of the patent and not with retrospective effect. The Act also contains wide and adequate provision for compulsory licensing by government as well as for export to other countries in certain circumstances.

[22] Agreement on Trade Related Aspects of Intellectual Property Rights, Apr. 15, 1991, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments - Results of the Uruguay Round vol. 31, 33 ILM 81 (1994) [hereinafter TRIPS].

[23] Sudip Chaudhuri, *TRIPS Agreement and Amendment of Patents Act in India*, ECONOMIC & POLITICAL WEEKLY (August 10, 2002).

Further, given the importance of the issues, the Government undertook broad-based and extensive consultations involving different interest groups on aspect of the law. These included scientists, academicians, economists, representatives of various industry sectors (such as pharmaceutical, biotech and software), chambers of commerce, private and public sector units, journalists, non-government organisations, representatives of State Government, lawyers and attorneys. During the wide ranging consultations, it emerged that not only were the amendments necessary to meet India's international legal obligations, but also that the Indian industry as a whole had transformed itself over the past few years and would stand to gain from a strengthened and balanced patent regime.

The major pharmaceutical companies have argued that compliance of the provisions of TRIPS would stimulate transfer of technology, encourage foreign direct investment, strengthen R&D investment and also ensure early introduction of new products in developing countries. These arguments are invariably backed by data on increased FDI in some countries where stringent IPRs were introduced. On the contrary, these were countered by arguments that these measures would push the prices for pharmaceuticals beyond the limits that could be afforded by the average Indian.[24] However the Indian pharmaceutical companies have stated that it is necessary at this stage for Indian companies to create their own intellectual property.

It is clear that an internal networking and co-ordination amongst different constituents of innovation chain has not only become necessary but imperative in order to bring down the time and costs of new drug discovery and its introduction in the market place. This affords a great opportunity to Indian R&D. The industry has since sought to reorient itself as a global player by increasing its emphasis on R&D which is reflected by the increased proportion of R&D expenditure to both investment and turnover.

(ii) Data Protection

Many companies have claimed that Data Protection is a necessity for the further growth of the industry given that the industry now spends a considerable amount of time and money in R & D and in conducting trials.

Clinical trials for pharmaceutical products in India are governed by the GCP (Good Clinical Practices) guidelines provided in Schedule Y of the Drugs and Cosmetics Rules, which provides for a number of mandatory requirements regarding their conduct, such as safety regulations. However, there are currently no provisions in Indian law regarding whether or not the data collected from such clinical trials

[24] Jean O. Lanjouw, "The Introduction of Pharmaceutical Product Patents in India: 'Heartless Exploitation of the Poor and Suffering'?", Working Paper No. 6366, National Bureau of Economic Research (1998), *available at* http://www.oiprc.ox.ac.uk/EJWP0799.pdf.

can be used by the Drug Controller General of India (the Indian regulatory authority) in its approval procedures for other drugs. Specifically, the debate in India centres on whether there should be data exclusivity, data protection or no provision at all. Both "data exclusivity" and "data protection" laws in the context centre on the information provided to the regulatory authorities by the entity conducting the clinical trials. Under a "data protection" law, the regulatory authority would be able to use this information in its decisions to grant approval to generic drugs that claim bioequivalence with the drug for which the clinical trial was undertaken, although it would not be permitted to disclose such information to others. On the other hand, under a "data exclusivity" law, the regulatory authority would not be permitted to use this information at all, thereby requiring the manufacturer of the generic drug to conduct its own clinical trials.

Take the following example to see how data exclusivity can increase the costs of pharmaceutical products and act as export inhibitors for generic manufacturers:

Company A gets approval for drug X from the FDA after conducting clinical trials in the USA. Company B applies for approval to the FDA claiming bioequivalence of generic drug Y with drug X. A data protection law means that the FDA can use the data from the clinical trials of X to approve Y, whereas data exclusivity means that the FDA cannot use such data for approving another drug and company B will have to conduct trials for Y, thereby increasing the cost of Y.

However, data protection can be a method for ensuring that data generated by a company in the course of its research or clinical trials, is not subjected to unfair commercial use, thereby staying in sync with the product patent regime. There has been some debate over whether or not Article 39.3 of TRIPS requires countries to enact data exclusivity laws – while some, such as the USA, New Zealand and the EU, insist that it does, others disagree because the article requires states to "ensure that the data are protected against unfair commercial use" and it is thought that the use of test data by a government regulatory body in making decisions regarding approval cannot be said to be commercial, even if approval would mean the commercialisation of the product. While it has been alleged that the Committee for the Protection of Undisclosed Information under Article 39.3 of the TRIPS Agreement has recommended a five year period of data exclusivity, the report for the same is yet to be released.

Appendix - V

Comparative Advantage of Indian Exports of Medicinal and Pharmaceutical Products

Table 27: Comparative Advantage of Indian Exports of Medicinal and Pharmaceutical Products (SITC 541)

Year	Indian pharma exports ($ mn)	Total Indian pharmaceutical ($ mn)	Share of pharmaceutical exports in total India's	World Pharmaceutical exports	Share of India in World pharmaceutical exports (%)
1996	431.20	19,641	2.2	49,829.40	0.87
1997	482.90	21,573	2.24	51,778.60	0.93
1998	585.80	25,022	2.34	59,723.70	0.98
1999	724.20	30,628	2.36	71,997.50	1
2000	814.00	33,107	2.46	77,833.90	1.04
2001	947.20	35,006	2.71	83,616.90	1.13
2002	933.70	33,463	2.79	94,572.10	0.98
2003	1,068.20	35,666	2.99	104,870.40	1.02
2004	1,255.20	42,378	2.96	107,481.70	1.17
2005	1,348.20	43,338	3.11	132,797.00	1.02
2006	1,760.00	49,293	3.56	151,861.60	1.16

Source: United Nations, International Trade Statistics Yearbook (various years)

Appendix – VI

Mergers & Acquisitions

The health-care costs are rising world-wide. Leading companies across the world are merging. Strategic alliances and collaborations are taking place in order to meet the increasing R&D budgetary requirement that exceed billion dollars each for many leading global pharmaceutical players.

Indian Drug manufacturers are pursuing foreign acquisitions due to their need to:

- Improve global competitiveness
- Move up the value chain
- Create and enter new markets
- Increase their product offering
- Acquire assets (including research and contract manufacturing firms, in order to further boost their outsourcing capabilities) and new products
- Consolidate their market shares
- Compensate for continued sluggishness in their home market.

Indian firms such as Glenmark, Jubilant Organosys, Nicholas Piramal, Ranbaxy Matrix Labs Aurobindo, Cadila, DRL, Sunpharma, NATCO and a few others made international acquisitions in areas of generics, marketing, custom synthesis, contract research, pharmacies, manufacturing assets. (Refer table 27 & Chart 24)

Often there is a significant overlap of expenditure in creating manufacturing assets or investing in R&D either in generics or in basic research resulting into wastages at national level. Consequently corporates have indulged either in acquisitions or mergers to avoid duplication of investments and capture larger market share at global place.

Table 28: Number of Overseas Acquisitions by Indian Pharmaceutical Industry (1995-Oct.2007)

Year	No. of Acquisitions
1995	**1**
1996	
1997	**1**
1998	**1**
1999	
2000	**1**
2001	**1**
2002	**6**
2003	**7**
2004	**12**
2005	**20**
2006	**14**
2007	**14**

Source : Exim Bank

Table 29: Selected International Acquisitions and Foreign tie-ins by the Indian Pharmaceutical Industry

Company	International acquisition (s)	Foreign alliances, JVS, and other tie ins
Nicholas Piramal	Pfizer-Morpeth (UK), Avecia Pharmaceutical (UK), Dobutrex brand acquisition (US), Rhodia's inhalation business (UK) , Biosyntech (NPIL Pharmaceutical) (Canada), Torcan Chemical (Canada), 51 percent of Boots (S. Africa), Bio Syntech	Ethypharm (France), Genzyme (US), Eli Lilly (US), Biogen Idec (US), Chiese Farmaceutici (Italy), Minrad (US), Pierre Fabre (France). Gilead Sciences (US), Allergan (US), Hoffmann-La Roche (Switzerland)
Ranbaxy	Terapia (Romania), Allen -GSK (Spain & Italy),Ethimed (Belgium), Betapharm (Germany), RPG Aventis (France), 40 percent stake in Nihom Pharmaceuticals (Japan), Brand-Veratide (Germany), Efarmes (Spain), Be-Tabs (S. Africa), Akrikhin (Russia), Basic (Germany), Ohm Labs (US)	GlaxoSmithKline (UK), Janssen-Ortho (Canada), IPCA Labs (US), Zenotech (India), Sonkel (S. Africa), Cephalon (US), Gilead Sciences (US), Schwarz (Germany)
Dr. Reddy's	Betapharm Group (Germany), Trigenesis (US), BMS Laboratories and Meridian Healthcare (UK), Roche's active ingredients business (Mexico), BMS Labs (UK)	Novo Nordisk, Bayer AG (Germany), Par (US), Novartis (Switzerland), Merck (Germany), Clin Tech, Pharmascience (Canada), ICICI (India), Merck (Germany), Schwartz
Marksans	Nova Pharmaceuticals (Australia)	NA
Aurobindo	Milpharm (UK), Pharmacin (Netherlands)	Gilead Science (US), Citadel (India)
Sun Pharmaceutical	Able Lab (US), Caraco (US), Valeant Pharmaceuticals (US & Hungary), ICN (Hungary), Caraco (US), MJ Pharmaceutical	Dyax
Dishman	Amcis (Switzerland), Solutia's Pharma (Switzerland)	Azzurro (Japan)
Orchid	Bexel Pharma (US)	Stada, Alpharma, Par, Apotex
Biocon	Nobex (US)	Centre of Molecular Immunology (Cuba)
Wockhardt	Wallis Labs (UK), CP Pharmaceutical (UK), Esparma (Germany), Pinewood Laboratories (Ireland), Dumex (India)	Pharmaceutical Dynamics (S. Africa)
Cadila	Alpharma (France-formulations), Dabur Pharma Redrock (UK)	Schering (Germany), Boehringer Ingelheim (Germany), Viatris (Germany), Novopharm (Canada), MCPC (Saudi Arabia), Cipharm (Ivory Coast), Geneva (US), GSK (UK), Ranbaxy (India), Mallinckrodt (US), Mayne (Australia), Shinjuki (Japan), Zydus Atlanta
Jubilant Organosys	Target Research Associates (US), PSI (Belgium), Trinity Laboratories (US)	NA
Matrix Labs	22 percent controlling stake in Docpharma (Belgium), Explora Lab (Switzerland), MCHEM (China), Fine Chemicals (S. Africa), API (Belgium)	Aspen, Emchem, Doc Pharma, Explora Labs
Glenmark	Kinger Lab (Brazil), Uno-Ciclo (Brazil), Srvycal (Argentina), Medicamenta (Czech), Bouwer Bartlett	Forest Labs (US), Lehigh Valley Technologies (US), Shasun (India), KV, Apotex (US)

Source: IBEF, Ernst & Young, The Economic Times, individual company web pages.

Appendix – VII

Clinical trials

Clinical trials usually employ Good Clinical Practice (GCP) guidelines developed by the International Conference on the Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and the principles contained in the Declaration of Helsinki on the "Ethical Principles for Medical Research Involving Human Subjects" (2004). Clinical Trials also use Good Laboratory Practice (GLP) guidelines for bioequivalence research. The ICH guidelines also provide internationally accepted ethical and scientific quality, standards for designing, conducting, recording and reporting trials. Besides, they also cover issues such as selecting and training trial investigators, gaining informed consent from trial participants and monitoring and quality assurance aspects. While the GCP has already been incorporated in Schedule Y of the Drugs and Cosmetics Act, 1940, more needs to be done by way of implementation of the same.

Several threats face this 'sunrise' sector. The growth of foreign competition has been rapid and the evolution of Indian quality standards has been slow. Sufficiently qualified personnel have also been difficult to come by. One major difficulty that this industry has faced in the past has been the uncertainty with regard to regulatory approval, due to the Drug Controller's reliance upon external experts from institutions such as the IMRC. The IMRC's *Ethical Guidelines for Biomedical Research on Human Subjects* was evolved in 2000 whereas; the Indian Good Clinical Practices only became available in 2001.[25]

The United States has mandated that all clinical trials reviewed and approved by the Food and Drug Administration (FDA) must be reviewed and approved by an Institutional Review Boards (IRB). IRBs, Independent Ethics Committees (IEC), or Ethics Review Boards (ERB) are formal groups of professionals designated to review and monitor research involving human subjects. India, in order to successfully undertake clinical trials needs to employ a greater number of proficient Institutional Review Boards, which have professional competence in addition to their knowledge of international and national regulations, applicable laws and standards of professional conduct and practice.

Clinical Trials are tied in (though not always) to the process of R & D and in R & D India faces stiff competition from China, Russia and the United States, since R&D often gravitates to countries with large domestic markets for the resulting products.[26] India will continue to have a significant advantage over the next few years, due to its proficiency in back office work, etc.[27]

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[25] Cygnus, "Contract Research and Manufacturing Services in India", May 2006, p.55.
[26] Diana Farrell, Noshir Kaka, and Sascha Starze, "Ensuring India's Off-shoring Future", 2005 Special Edition, *McKinsey Quarterly*, available at **www.mckinsey.com**.
[27] *Id.*

While some fiscal incentives already exist, such as the waiver of customs duty for import of clinical trial samples and income tax benefits, specific state level incentives need to be given with regard to land and schemes for the setting up of these institutions.

A single window for regulatory clearance could be created which operates within a fixed time frame, allowing for the delivery of results within tight deadlines.

Research Design: Research design is one of the factors determining success in clinical trials. Indian firms while designing their clinical trials need to place greater emphasis on simple and highly informative schedules in the design, information about the subject, clinical data of the subject, disease parameters and planning. The number of subjects in each stage, detailed procedures for conducting and analyzing the data also need to be explained properly.

Infrastructure: To carry out clinical trials successfully, Indian firms need to scale up their infrastructure facilities such as hospitals with modern imaging technologies, facilities like ECG, Biochemistry Laboratory, X-ray Units, CT and MRI and round-the-clock availability of specialists.

Data management: Clinical trial data management is of prime importance in the selection of subjects, accuracy of subject recruitment rates and for obtaining real estimates of diseases of global interest. Leveraging the country's strong IT base, companies, institutions and Contract Research Organisations (CROs) involved in clinical trials should expand their data management segments creating infrastructure that can integrate huge amounts of data from genomics, proteomics and healthcare facilitating critical conversion of data into drug discovery and new treatments, thereby, cutting costs and shortening the development cycle.

The incentives mentioned in the draft National Pharmaceuticals Policy of 2006 such as exemption of service tax for direct investment in the field of clinical development and data management, exemption from import duty, improved regulatory infrastructure and some form of protection for undisclosed test data etc., ought to be acted upon.

Currently, India is experiencing a growing number of collaborations between Indian and foreign firms in the domestic market, especially involving the biotechnology sector, in a wide variety of areas such as collaborative R&D (including drug discovery and clinical trials), co-marketing and manufacturing.

India and China's drug outsourcing discovery markets combined are currently worth around $7.3 billion and driven by government initiatives to diversify the drug discovery portfolio and develop infrastructure, are set to reach $19.8 billion in 2011, say analysts at Frost & Sullivan.

There are dozen GLP approved research laboratories in India having several facilities. The total number of different facilities available with these labs is tabulated in the Table 27 below.

Table 30: GLP Approved facilities in India

Facility Type	No. of facilities
Toxicity studies	11
Mutagenicity studies	9
Analytical and clinical chemistry testing	8
Physical-chemical testing	7
Environmental toxicity studies on aquatic & terrestrial organisms	4
Residue studies	3
Studies on behaviour in water, soil and air; bioaccumulation	2
Studies on effects on mesocosms and natural ecosystems	1
Studies on natural enemies and predators	1
Safety Pharmacology and Pharmacokinetic Studies	1
Others (drug metabolism & pharmacokinetics [DMPK] and tissue distribution studies)	1

Abbreviations

ADMA	-	Ayurvedic Drug Manufacturers Association
AIDs	-	Acquired Immune Deficiency Syndrome
ANDA	-	Abbreviated New Drug Application
API	-	Active pharmaceutical ingredient
C&PC	-	Chemicals & Fertilizers
CAGR	-	Compound annual growth rate
CDSCO	-	Central Drugs Standard Control Organisation
CENVAT	-	Central Value Added Tax
cGMP	-	Current Good Manufacturing Practices
CIS	-	Commonwealth of Independent States
CMIE	-	Centre for Monitoring Indian Economy
CMOs	-	Contract Manufacturing Organisations
CNS	-	Central Nervous System
CPP	-	Certificate of Pharmaceutical Product
CRAMS	-	Contract Research and Manufacturing Services
CROs	-	Contract Research Organisations
CSFs	-	Colony Stimulating Factors
CSIR	-	Council for Scientific and Industrial Research
CVS	-	Cardio-Vascular System
DBT	-	The Department of Biotechnology,
DCGI	-	Drug Controller General of India
DEPB	-	Duty Entitlement Pass Book
DGFT	-	Director General of Foreign Trade
DMFs	-	Drug Master Files
DPCO	-	Drug Price Control Order
DS&T	-	he Department of Science and Technology,
DSIR	-	Department of Scientific and Industrial Research
ECGC	-	Export Credit Guarantee Cooperation
EDI	-	Electronic Data Interchange
EIU	-	Economist Intelligence Unit
EMEA	-	European Medicines Agency
EOU	-	Export Oriented Unit
ERB	-	Ethics Review Boards Institutional Review Boards
EU	-	European Union
FDI	-	Foreign direct investment
FTA	-	Free Trade Agreements
FTE	-	Full Time Equivalent
FTP	-	Foreign Trade Policy

GCP	-	Good Clinical Practices
GDP	-	Gross Domestic Product
GLP	-	Good Laboratory Practices
GSK	-	GlaxoSmithKline
HIV	-	Human immunodeficiency virus
HTS	-	Harmonized Tariff Schedule
ICAR	-	The Indian Council of Agricultural Research
ICH	-	Pharmaceuticals for Human Use
IDMA	-	Indian Drug Manufacturers Association (IDMA)
IEC	-	Independent Ethics Committees
IITs	-	Indian Institutes of Technology
IMRC	-	Indian Medical Research Council,
IP laws	-	Intellectual Property Laws
IPR	-	Intellectual property rights
IRB	-	Institutional Review Boards
ISM	-	Indian System of Medicines
IT	-	Information Technology/Income Tax
L&D	-	Learning & Development
LAC	-	Latin American Companies
M&A	-	Mergers and acquisitions
MCA	-	Medicines Control Agency
MNC	-	Multinational Corporation
MODVAT	-	Modified Value Added Tax
MPCs	-	Multinational Pharmaceutical Companies
NCE	-	New chemical entities (new patented drug)
NDA	-	New drug applications
NDDS	-	New Drug Delivery Systems
NIP	-	Non Infringing Process
NIPER	-	National Institute for Pharmaceutical Education and Research
NITs	-	National Institutes of Technology
NMPB	-	National Medicinal Plants Board
NOC	-	No Objection Certificate
NTB	-	Non-Tariff barrier
OECD	-	Organisation for Economic Cooperation and Development
OTC	-	Over-the-counter drugs (dispensed without prescription)
PKDM	-	Pharmaco Kinetic and Drug Metabolism
R&D	-	Research and development
ROCE	-	Return on Capital Employed
ROW	-	Rest of the World
SEZ	-	Special Economic Zones
SION	-	Standard Input-Output Norms

SPV	–	Special Purpose Vehicles
TGA	-	Therapeutic Goods Administration
TRIPS	-	Trade-Related Aspects of Intellectual Property Rights
UK MHRA	-	United Kingdom Medicines and Healthcare Products Regulatory Agency
UNICEF	-	United Nations Children's Fund
US FDA	-	United States Food and Drug Administration (FDA)
VC	-	Venture Capital
WTO	-	World Trade Organization

Definitions

Abbreviated New Drug Applications (ANDAs): An application submitted to the U.S. Food & Drug Administration by a generic drug manufacturer challenging a patent held by an innovator company. Once approved, an applicant may manufacture and market the generic drug product of an existing formulation to the American public.

Active pharmaceutical ingredient (APIs): The primary, active ingredient(s) of a final pharmaceutical product, produced in the first stage of pharmaceutical production and usually in bulk quantities.

Biologicals: Medical preparation made from living organisms and their products, such as insulin, erythropoietin, and vaccines.

Blockbusters: industry term referring to drugs with very large sales, generally in excess of $1 billion.

Branded generics: Generic drugs for which a drug manufacturing company has attached its brand name and may have invested in its marketing to differentiate it from other generic brands.

Brand name drugs: innovator drugs patented by MNC pharmaceutical companies to prevent them from being copied or reverse engineered by other companies.

Bulk drugs: The active chemical substances in powder form, the main ingredient in pharmaceuticals – chemicals having therapeutic value, used for the production of pharmaceutical formulations. Major bulk drugs include antibiotics, sulpha drugs, vitamins, steroids, and analgesics.

Drugs: There are two types of drugs: bulk drugs (intermediates) and formulations.

Drug intermediates: These drugs are used as raw materials for the production of bulk drugs, which are either sold directly or retained by companies for the production of formulations.

Drug Master files (DMFs): Generic registration applications filed with the U.S. FDA in order to allow the active pharmaceutical ingredients (APIs) to appear in marketed drugs.

Essential drugs: Drugs classified as essential by the Indian government consist of antibiotics, antibacterials, anti-TB, penicillin and its salts, anti-parasitic, cardiovascular drugs, erythromycin and its preparations, vitamins and pro-vitamins, vaccines (polio, human and veterinary), preparations containing insulin, caustic and other hormones, and tetracycline and its preparations. Indian companies dominate this class of drugs with a domestic Indian market share of 71 percent. These drugs are subject to government price controls.

Formulations: Drugs ready for consumption by patients (generic drugs) sold as a brand or generic product as tablets, capsules, injectables, or syrups. Formulations can be subdivided into two categories: generic drugs and branded drugs.

Generic drugs: Copies of off-patent brand-name drugs that come in the same dosage, safety, strength, and quality and for the same intended use. These drugs are then sold under their chemical names as both over the counter and prescription forms. Also, referred to as unbranded formulations.

Innovator drugs: Are drugs with patents on their chemical formulation or on their production process. They have been tested and approved by the U.S. FDA after extensive clinical trials.

New Drug Applications (NDAs): the vehicle through which drug innovators formally propose that the U.S. FDA approve a new drug for sale and marketing in the United States.

Pharmaceuticals: Are used to prevent, diagnose, treat, or cure diseases in humans and animals.

Plain vanilla generics: commodity generics that are “off-patent” in the regulated markets. They offer little or no innovative value over the innovator’s product.

Prescription drugs: Medicines that encompass two classes, innovator drugs and generic drugs.

Proprietary drugs: Drugs that have a trade or brand name and are protected by a patent.
West/ Western: The United States, Canada, and Western Europe.