Pharmaceuticals - Executive Summary

Drugs and pharmaceutical industry plays a vital role in the economic development of India. It is one of the most advanced sectors in India, acting as a source for various drugs, medicines and their intermediates as well as other pharmaceutical formulations. Indian pharmaceutical industry employs about 350,000 people and an estimated 400,000 doctors and 300,000 chemists. It ranks among the top five countries by volume (production) and accounts for about 10% of global production. The industry's turnover has grown from a mere US$ 0.3 billion in 1980 to about US$ 21.73 billion in 2009-10[1].

The products manufactured by the Indian pharmaceutical industry can be broadly classified into: Bulk drugs (active pharmaceutical ingredients - API) and Formulations. Bulk Drug Industry is the backbone of the self-reliant Pharmaceutical industry in India, playing a significant role in improving the health standards of the people. The bulk drug segment contributed to around 60% to India's pharmaceutical sector exports of US$ 14.5 billion in 2010. Bulk drugs segment exports have grown consistently and witnessed a CAGR of around 15% during the five year period 2005-10. Given the current and expected future contribution of bulk drugs segment, improvements in the same is expected to have far reaching and large impact on overall competitiveness of the Indian pharmaceuticals industry.

Bulk Drugs have four core manufacturing processes viz. Drug Discovery, Drug Development and Drug Manufacturing. Absence of strong Raw material production &Component manufacturing for Drug Manufacturing and absence of strong drug discovery infrastructure are having widespread impact on the overall competitiveness of bulk drugs. An improvement in these processes, which are the weakest links as well as essential for growth of other processes, would give impetus to overall competitiveness of the industry.

Market size of the global bulk drugs in 2009 was US$102.35 billion and was dominated by the U.S.A.& China. The global export of bulk drugs in 2010 stood at US$ 370 billion and was dominated by the USA contributing to 11% of the global exports, closely followed by China with a contribution of around 8.50%. India stood 14th contributing to around 2.3% of global exports.[2] Amongst the top 10 exporting nations, China has shown the highest CAGR of around 21% for a 5 year period 2005-10.

China's pharmaceutical industry has been aided by large scale manufacturing capabilities and Government support over the years. Chinese API manufacturers have integrated themselves into the global supply chain for both innovator pharmaceutical and generics companies worldwide and are no longer limited to merely supplying intermediates and commoditised bulk drugs. China's leading position within the global bulk drug market has been driven by cost leadership (lower than India) and large scale manufacturing capabilities in certain product segments such as antibiotics and vitamins. Additionally, in comparison to India, Chinese API manufacturers also benefit from China's extensive presence in intermediates with strong technological capabilities in fermentation, thereby ensuring ample availability of raw materials. The strong manufacturing capabilities coupled with greater regulatory compliance and improving intellectual property (IP) protection has helped Chinese manufacturers increase supplies to regulated markets.

[1] D&B Analysis
[2] ITC, D&B Analysis (In absence of exact definition of HS Codes for bulk drugs, HS Code 29 (Organic Chemicals) has been considered for bulk drugs)

USA has benefitted from a supportive domestic environment for the development & commercialization of pharmaceuticals. U.S. government has enacted several R&D tax incentives& schemes and schemes like 'Orphan drugs act' that have led to growth of the industry.

A comparative assessment of Indian pharmaceuticals goods industry vis-à-vis that of competing countries point out to the following key points:

1. ***Government's policy focus is a key to global success of pharmaceutical industry***

Chinese government has played a major role in development of pharmaceutical industries in its country. The Chinese government has played an important role by laying new regulations and decrees regarding drug production and distribution, which enabled state owned pharmaceutical companies to become more market oriented. The Chinese government has also contributed in development of drug R&D capabilities by creating an innovation-oriented environment. The Japanese government deregulated the pharmaceutical industry during the 1960s and since then several reforms have taken place including FDI liberalisation in the sector, changes in the patent laws, and simplification of accreditation of drug manufacturers. The newly-created PMDA agency was introduced in 2004 with a view to improve drug approval times and bring them more into line with their US and European counterparts. The market is therefore increasingly open to overseas products, and many domestic companies are being forced into measures such as mergers and expansion of R&D facilities in a bid to ensure survival in the marketplace. In the Indian pharmaceutical industry, price regulations, inadequate or weak drug control infrastructure at state & central level, etc. impacts the pharmaceutical industry. At present, pricing of 74 bulk drugs and their formulations, which account for a large share in the retail pharmaceutical market, are controlled by the Drug Price Control Order (DPCO)-1995. Direct control on prices of medicines discourages the industry from producing these medicines, defying the very purpose of making essential medicines available to masses at affordable prices. Therefore, the government needs to take a balanced approach towards price control, after taking into account its repercussions on drug availability on the one hand and drug affordability on the other.

2. ***Better investment climate in competing countries gives them a competitive edge***

China has emerged as an attractive market to many multinational pharmaceutical companies owing to its large market size, increasing government spending on healthcare, government reform plans to restructure the highly fragmented industry, emphasis on encouraging innovation, and improved intellectual property protection. Moreover, the government provides various tax and other incentives to foreign investors in the sector. Although foreign enterprises are subject to 30% corporation tax and additional 3% local corporation tax, the foreign companies generally end up paying lower than full corporate tax due to various tax exemptions. The foreign companies enjoy similar tax concessions as domestic companies in the Special Economic Zones. The Irish pharmaceutical industry has been a major international success story. Irish Industrial Development Agency (IDA) played a major role in attracting foreign investments in the sector. The sector that was almost non-existent until the 1960s, took off in the 1970s following the IDA`s adoption of fine chemicals as one of its target sector, thereby leading to a series of manufacturing investments, notably by US and UK-based companies. Although Indian pharmaceutical has globally recognized capabilities in generics production, it lacks in terms of investments in API production which requires inter-alia cheap power and other infrastructure facilities. Some of the areas where Indian industry is lacking are: inadequate GLP compliant animal facilities, lack of biological sample storage facilities and inadequate shared infrastructure for optimal capacity utilization.

3. ***Tax incentives and subsidies have improved competitiveness of players in major markets***

Chinese government provides several incentives to the domestic pharmaceutical industry, such as tax reliefs and direct funding opportunities. The pharmaceutical firms are eligible for various tax incentives such as High/New Technology Enterprise (HNTE) incentive, CIT super deduction, IT exemption for transfer of technology, and tax refunds which may extend up to 100%. The government of United States also has introduced several forms of tax credits over the years like Research Tax Credit, Orphan Drug Credit and Possessions and Puerto Rican Economic Activity Tax Credit etc. These have helped a large number of drug manufacturers engage in new drug discovery and prompted them to spend more on research than they otherwise would. The drug industry has been a leading beneficiary of the research credit: in 2006, it claimed $902 million in research tax credits, or 12% of the total amount of such claims by all industries. Since the orphan drug credit was enacted in 1983 as one of a series of measures aimed at stimulating increased investment in the development of new drugs to treat rare diseases and conditions, at least 325 such drugs have gained regulatory approval in the United States. Indian government too has realized the importance of tax incentives and subsidies and hence offer tax breaks to pharmaceutical industry in the form of weighted tax deduction for R&D expenditure, low customs duty and nil excise duty on specified lifesaving drugs.

4. ***Investments in R&D boost competitiveness of pharmaceutical sector***

Major competing countries have made huge investments in R&D for pharmaceutical sector, providing several tax and non-tax incentives and direct subsidies to the industry players. Besides incentives, the governments have also established specialized institutes and research facilities. Pharmaceutical industry in the USA has been a pioneer in terms of the discovery of new cost effective and life-saving drugs. U.S. firms conduct 80% of the world's research and development in biotechnology and hold the intellectual property rights to most new medicines. According to the Pharmaceutical Research and Manufacturers of America (PhRMA), manufacturers spent nearly US$67.4 billion on R&D in 2010. Programmes like Small Business Innovation Research (SBIR) and Small Business Technology Transfer program (STTR) have strengthened the role of small business in meeting Federal R&D needs for pharmaceutical industry. The program used small businesses to stimulate technological innovation and increased private sector commercialization of innovations.

Chinese government's national innovation policies and the IPR policy have played an important role in fostering China's drug R&D. The government runs a national program 'Major New Drug Creation' which includes budget allocation of almost one billion dollars to support domestic pharmaceutical companies in developing new drugs with independent IPR. The funding for this project is expected to increase to about 4.3 billion dollars by 2020. Pharmaceutical companies in China are eligible for various tax incentives for conducting R&D and other operations. Some of them being: High/New Technology Enterprise (HNTE) incentive; CIT super-deduction; Income tax exemption for the transfer of technology; and Tax concessions/ refunds.

In India, the overall spend of pharmaceutical industry on R&D is estimated at a mere 2% of sales as against 10-20% global average. The Indian government has taken several policy initiatives for strengthening R&D in the pharmaceuticals sector such as fiscal concessions, tax deductions for R&D expenditure, and has also established premier research institutes for the pharmaceuticals sector such as National Institute of Pharmaceutical Education and Research (NIPER).

5. ***Trade barriers could affect competitiveness of Indian exporters***

Trade agreements of developed markets with other countries could affect the prospects of Indian pharmaceutical exporters. For instance, USA has entered into FTAs with several developing

countries (example Morocco-USA FTA). Such FTAs also include provisions for extension of patent terms, which would affect exports of generics from India.

Indian exporters are also subjected to non-tariff barriers such as long transaction time 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.

6. ***Costs and availability of critical input material- raw material and technology***

China is better endowed with raw materials such as phosphorous, potassium and sulphur, so it can produce bulk drugs at 10 per cent of the cost in developed countries. India is relatively weak in fine chemicals and relies on China for its imports. Further, there is lack of availability of critical raw materials like urea, hydrazine hydrate etc. for which India has to rely mainly on imports from countries like Korea and China. This increases India's raw-material cost manifolds. Moreover, India does not have enough indigenous capability for manufacturing analytical instruments and has to rely on imports which further leads to increase in the cost.

7. ***Quality accreditations increases the market reach of competing countries***

Quality accreditation is an important parameter for competitive advantage as it enables a firm to increase its market reach. China's State Food and Drug Administration (SFDA) have been making constant efforts to upgrade quality of drugs produced in China. A new set of Good Manufacturing Practices (GMP) in China came into effect in March 2011, which upgrades drug quality standards of the country at par with international standards, thereby making Chinese drug companies internationally competitive. India is signatory to the WHO certification protocol on the quality of pharmaceuticals products and has therefore accepted the WHO-GMP standards as an integral part of the standards for export of pharmaceuticals products. As per arrangement, WHO-GMP certification is granted by the office of the DCGI (CDSCO) and State FDAs. It is estimated that at present about 800 units are certified by CDSCO for WHO-GMP production. There are about 10,000 plus pharmaceutical SME Units in the country, hence the number of firms with certification is very less as compared to global standards.

Based on analysis of the current status and international norms & standards, the gaps & issues in the Indian Pharmaceuticals Goods industry can be summarised as following:

S.No.	Impact Areas	Issues
1	Scalability	Fragmented nature of the Indian pharmaceutical industry- Very few companies being large enough to bear the transactions costs associated with entry regulations of the developed markets.
		Important facets of pharmaceutical industry such as intellectual property creation, facility design and maintenance, global regulatory affairs, legal compliances, etc. being conducted by limited large players
		Lack of Cold Storage space & facilities suited to specific pharmaceutical products, with automated humidity & temperature control mechanisms
2	Cost Efficiency	Stringent pricing regulations affecting the profitability of pharmaceutical companies.
		Rising prices of sugar leading to overall increase in production costs.
		Land locked regions like Pune, Hyderabad, Indore etc. which contribute majority share of Indian Pharmaceutical trade incur higher costs of transportation
		Lack of availability of petrochemicals used for manufacturing of bulk drugs in India resulting in reliance on imports.

		Lack of availability of reference standard products as per Indian Pharmacopeia (IP) resulting in dependence on imports for these batch specific, time limited reference products. Hence overall cost of testing increases.
3	Productivity Optimization	Lack of advanced lab and related infrastructure for drugs testing, especially in segments like antibiotics.
		Low investments in innovative R&D
		Inadequate medical devices and equipment industry. Critical equipment like analytical instruments etc. not available indigenously
4	Quality Excellence	Lack of ability to compete with MNCs for discovery of new drugs, research & commercialization of molecules on a worldwide basis.
		Lack of resources with the Central Drugs Standards and Control Organization (CDSCO) leading to delays in clearances for new drug trials, pharmacovigilance and assistance to the willing industry members
5	Sustainability	Stringent pricing regulations affecting the profitability
		Lack of awareness of global testing standard for drugs among SMEs
		Lack of proper regulatory framework for bio-similar drugs

The analysis of various facets of the global and the Indian Pharmaceuticals industry clearly shows that India needs to look at multiple interventions including in the areas of Regulatory framework, Investment policies, Trade policies, Fiscal policies, Infrastructure, R&D, Skill, Financing, Process, Collaboration and Technology. These interventions have been detailed in the main report.

However, recommendations only related to technology and research & development have been detailed which could form part of several schemes undertaken by Department of Science & Industrial Research in this section.

Intervention 1 : Focused scheme to improve scale of operations	
S.No.	**Tasks**

1	• Incentives to domestic firms who invest more than a threshold amount in fixed assets.
	• Focused scheme to improve market access of domestic firms:
	  • Financial assistance to domestic firms who wish to acquire international brands, equity holdings, controlling interests, intellectual properties etc.
	  • Financial assistance for improved access to developed markets. Assistance needs to be provided for: product dossier development expenses, regulatory filing costs and potential litigation costs.
	  • Financial assistance to domestic firms for participating in international trade events so as to provide them access to export markets.
	  • Scheme to introduce 'Shared Marketing Services' for the small companies. Facilitate marketing co-operation in destination countries, by having a common entity to 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 minimize the overall investments in the marketing.

Intervention 2 : Focused scheme to improve raw-material competitiveness	
S.No.	**Tasks**
2	Focused scheme for encouraging domestic manufacturing of critical raw-materials and intermediates/inputs for bulk drugs. The scheme will supplement the objectives of the Cluster Innovation Centres to bridge the demand-supply gaps in multiple aspects of a business and drive need-based innovation in the industry clusters .Some of the steps

	that may be adopted are: • Compile a list of critical raw-materials which have enough demand in India but very limited domestic production to match the demand. (Some of them are non-agricultural urea, hydrazine hydrate etc.) • Create a centralized fund which could be utilized for acquisition of international companies/assets operating in various raw-material categories. For the same designate an implementing agency to invite shortlist and grant the funding to the SMEs.
Intervention 3 : Focused scheme for increasing SME's competitiveness by improving the compliance standards	
S.No.	**Tasks**
3	Focused scheme for encouraging SME's to upgrade to WHO-GMP standards as well as provide access of these standards to new units. The scheme aims to strengthen the manufacturing standards used by industry by providing access to knowledge for WHO-GMP standards. Various activities that may be performed for the same are: • Creation of document for necessary requirements for WHO-GMP manufacturing standards. • Arrange for training/awareness programmes in all the small & big pharmaceutical clusters targeting all the SSI. • Dissemination of information on WHO-GMP standards for enterprises setting up new units in the sector. • Financial support for SSI units who are willing to upgrade to WHO-GMP standards.
Intervention 4 : Database support & technology support to SMEs	
S.No.	**Tasks**
4	Provide database support for SMEs in the following areas: • Technology- and innovation-related international journals from major publishers • Country wise SOPs for testing various products shall be explained in detail. • Testing labs available in Indian and abroad along with details of tests conducted by them, fees for conducting the tests etc. • Industrial status of these countries also needs to be integrated. The software should be integrated with government schemes available as well for enabling SMEs to conform to these standards.
Intervention 5 : Foster R&D and encourage new drug development	
S.No.	**Tasks**
5	Launch a national level scheme to encourage both academia & industry to target efforts towards new drug development. The scheme focuses on creating an enabling environment for collaborative research between Industry and Universities/Public Funded Research Institution. The scheme may target to implement the following: • Provision for funding up-gradation of labs in the private and government sector with sharing basis on 50-50 pattern for the lab up-gradation for equipment deployed for drug development under specifically identifiable projects. • Incentive scheme to reward any breakthroughs in drug discovery by academia or industry. • Incubation centres for providing supportive framework for the researcher that enables him to turn a technological idea that has an economical-marketing potential into a product of interest for investors.

The interventions mentioned above are further prioritized on the basis of their role in fulfilling various objectives* of the Government of India for the growth of the manufacturing sector. Each intervention is tagged with the objective that it may help achieve. The intervention impacting maximum number of objectives has been prioritized for implementation.

*These objectives have been picked up from "PM's Group Report on Measures for Ensuring Sustained Growth of The Manufacturing Sector", "National Manufacturing Policy 2006" and "National Manufacturing Policy 2011".

Intervention	Government Objectives					
	Building Strong Capacity & Scale	**Employment**	**R&D**	**Skill Development**	**Local Value Addition**	**Technology Adoption**
Focused scheme to improve scale of operations	✔	✔		✔	✔	✔
Database & technology support to SMEs			✔	✔	✔	✔
Foster R&D and encourage new drug development			✔	✔	✔	
Focused scheme to improve raw-material competitiveness	✔	✔			✔	
Focused scheme for increasing SME's competitiveness by improving the compliance standards				✔		✔

Pharmaceuticals: Innovation Framework

Knowledge Creation & Commercialization

- Focused scheme for encouraging domestic manufacturing of critical raw-materials and intermediates/inputs for bulk drugs: Tax holidays for overseas companies for JV's with Indian partners, reduced excise duty on inputs etc.
- Launch a scheme for improving cold chain infrastructure for pharmaceuticals and refrigerated Vehicles.
- Focused scheme to support infrastructure creation for setting up green-field medical devices and equipment parks.
- Launch a national level scheme to encourage both academia & industry to target efforts towards new drug development & commercialization of the same.
- Focused scheme to improve scale of operations of domestic companies : Incentivization for higher investments, direct & indirect subsidy schemes, assistance for market access.

Inclusive Innovation

- Develop software, under the technical guidance of DCGI, for helping the SMEs in achieving various regulatory compliances.
- Focused scheme for encouraging SME's to upgrade to WHO-GMP standards.
- Provide database & technology support to SMEs

Knowledge Diffusion & Absorption

- Set up an implementing agency to enable Indian small scale units to adopt 2D barcoding which has been made a regulatory requirement for export of medicines by DGFT.
- Set up a national implementing agency to undertake project of planning, implementing and monitoring the program for incorporating RFID in cold chain and logistics to improve the traceability in the pharmaceuticals supply chain.
- Set up a designated R&D center for bulk drugs as a separate profit center.
- Set up a Pharmaceutical Nanotechnology Center to perform focused research on use of nano-materials for emerging industries like medical devices industry and for new innovative drug delivery systems
- Launch a scheme to set up Joint testing and lab facilities for certification of Indian pharmaceuticals products imported into various focus countries in BRIC, ASEAN, CIS, IBSA markets.
- Set up training centers for "International Manufacturing Standards" at major bulk drug clusters

Support Mechanisms

Skills

- Database support to SMEs including country wise SOPs for testing, technology related journals etc.
- Awareness of international manufacturing standards.
- Training centres for "International Manufacturing Standards

Policy

- Policy support from government so as to resolve raw-material issues faced by Indian bulk drugs industry.
- Tax-holidays
- Reduction in excise and customs duty of critical chemicals and raw materials
- FTAs for improved market access

R&D

- Dedicated research for bulk drugs.
- R&D in the area of nano-materials, bio-similars.
- Scheme to encourage both academia & industry to target efforts towards new drug development.
- Incentive scheme to reward breakthroughs in drug discovery

Infrastructure

- Joint testing labs with international companies.
- Training centers for international manufacturing standards.
- Cold chain facilities
- Shared Marketing Services Centers
- Incubation centres

Collaboration

- Collaboration for testing labs
- Collaboration for domestic raw-material manufacturing
- Collaboration for R&D and standardization