Pharmaceuticals – Indian Regulatory & Policy Environment

Regulatory Bodies

The primary regulatory body for pharmaceutical sector is CDSCO - Central Drugs Standard Control Organization, commenced in 1940. Department of chemicals and petrochemicals (DCP) was commenced in 1991, to handle the policy and planning aspect of chemical, petrochemical and pharmaceutical industries. In order to fix and revise the prices of controlled bulk drugs, National Pharmaceutical Pricing Authority (NPPA) was commenced in 1994.

A summary of regulatory and policy environment in Indian Pharmaceutical industry is provided below:

Price	DPCO introduced in 1970, presently DPCO 1995 in force DPCO authorizes the govt. to control prices of 74 bulk drugs & their formulation NPPA does price fixation/revision and updating list of drugs under price control Direct price control discourages the industry from producing these medicines
Product & Quality	CDSCO lays down standards for the drugs, cosmetics, diagnostics & device that manufacturer should follow Good Manufacturing Practices (GMP) for plants & materials National Pharmaceutical Policy seeks to strengthen the GMP norms
Patents	Patent Act, 1970 > Patent (Amendment) Act 2005 With amendment the following have changed Scope of patentability Royalty Amount Immunity for generic production Export Opposition to the grant of patent Terms of patent Compulsory Licensing
Others	Data protection: TRIPS provides protection for 'undisclosed information' under IPR The information being protected is generated during clinical trials

With the introduction of Patents (Amendment) Act 2005, there has been a shift in strategy followed by leading Indian companies; they are moving on to developing new drugs, exporting to regulated markets and getting into cooperative agreements with MNCs. This works to India's advantage due to the issues faced by MNCs such as sluggish sales of patented drugs in home markets, declining R&D revenues and rising costs. To deal with these issues and to focus on their core competency i.e. drug discoveries and marketing of the drug, MNCs have increasingly participated in CRAMS, co-marketing alliances, outsourcing of research and clinical trials.

Key Government Initiatives

In the XIIth plan, Indian government plans to increase the public expenditure on healthcare to 2-3% of GDP. Government has offered tax-breaks to the pharmaceutical sector, significant government allocations on healthcare spend include a five year tax break for opening hospitals anywhere in India. To ease the burden of R&D cost which is enormous, units are eligible for weighted tax deduction at 200% for the R&D expenditure incurred. Emphasis is on streamlining procedures covering development of new drug molecules, clinical research etc. Government also has two new schemes—New Millennium Indian Technology Leadership Initiative and the Drugs and Pharmaceuticals Research Programme to aid the sector in its development.

Tax incentives and subsidies

Several incentives are offered to pharmaceutical players. These are in the form of excise duty exemptions, income tax holidays, investment subsidy (on capital investment) and interest subsidies.

The list of various schemes and programmes for the Indian pharmaceutical industry as per the XIIth plan are detailed below.

S.No	Scheme	Brief description
1	**INDUSTRY PROMOTION&DEVELOPMENT**	
1.1	**Existing Schemes from 11th Plan – Continued**	
(i)	Pharma Promotion and Development Scheme (PPDS)	Grant assistance for Industry Studies, Workshops, Seminars, etc.
(ii)	Intellectual Property Rights Facilitation Centres	Capacity building Grant assistance (capital and revenue) for setting up of IPR centres by Pharmaexcil, Industry bodies, etc. to assist industry in IPR matters
1.2	**New Schemes**	
(i)	International Pharma Cooperation Initiative (IPCI)	Setting up of Joint testing and lab facilities for certification of Indian pharmaceutical products, development of locally sustainable formulations and drug delivery systems and other mutually beneficial schemes
(ii)	Up-gradation of SMEs to WHO-GMP standards	Interest based subsidy scheme at the rate of about INR 1 cr. per unit of assistance to be implemented in partnership with IDBI /SIDBI for upgrading SMEs to WHO-GMP manufacturing standards to capitalize on the Generics Opportunity – about 1200 units out of about 10,563SMEs in the country have availed so far.

(iii)	Capacity building through training of 5000 Working Professionals in WHO-GMP	To provide manufacturing capability up-gradation assistance for capital expenditure, skill development of personnel required for such up-gradation and sustenance of supply of skilled personnel.
(iv)	Up-gradation of SMEs to USFDA/EDQM/TGA and other International Standards	Specific assistance for standards higher than WHO-GMP to selected SMEs – 250 in numbers to build **Competitiveness** of very high standards and second line of internationally capable industry for high value pharmaceuticals products for strong regulated but high value markets
(v)	Setting up of one National and five Regional Formulation Development and Manufacturing standards training centres	Scheme to set up Formulation development centres to tap the patent cliff opportunity and become global leader in Generics and Bio-similars
(vi)	Establishment and up-gradation of 10 Pharmaceuticals Growth Clusters	Infrastructure building for pharmaceuticals industry particularly for SMEs – building on strength of existing Clusters so as to provide infrastructure gaps for higher production including taking care of environment, power and labs testing needs, etc.
(vii)	Infrastructure support for Cold Chain for high end drugs for exports	To enhance exports capability for high end drugs requiring exact cold chain standards till the time they are exported from the country in light of stringent developed market requirements
(viii)	Scheme for environment standards compliance and required infrastructure support including capacity building	Providing financial and technical assistance to improve financial sustainability of SMEs on one hand and also safeguard the environment from the hazards associated with the unplanned growth of the industry
2	**R&D ,CAPACITY BUILDING ANDEMPLOYMENT**	
2.1	**Continuing Schemes**	
2.1.1	**For NIPER Mohali**	
(i)	The continuation of the PG and the PhD education	The continuation of the PG and the PhD education at present strength levels would require budgetary support which will be provided in the scheme.
(ii)	Capacity Enhancement for supporting required industry human resources and capacity building requirement by the Institute	- Additional 1000PGs and PhDs - Training Industry and Regulatory personnel - Public Health and Pharmacovigilance training - Infrastructure Up-gradation
2.1.2	**For New NIPERs**	

(i)	Permanent establishment and operation of 6New NIPERs	
2.1.3	**Other Schemes**	
(i)	Setting up of National Center for Phyto-pharma development	Major capital expenditure of about INR 100 cr. being met from DONER. Present allocation sought for initial years operation as per advice from DONER
(ii)	GLP/GCP/Animal House Lab Schemes	For setting up of GLP compliant Labs, GCP compliant Lab and an Animal House Lab on PPP basis is under implementation
(iii)	Continuing R&D Schemes For NIPER Mohali	NIPER Mohali is presently implementing a number of projects in R&D for various areas like neglected diseases, infectious diseases, vector borne diseases, etc. In addition a number of projects are being implemented for Public health, Pharmacovigilance, Regulatory capacity building for academia and industry, etc.
(iv)	Continuing scheme at New NIPERs	Joint development of Tuberculosis related drugs at NIPER Ahmedabad andAIIMS, Delhi
2.2	**New Schemes**	
(i)	Establishment of New NIPERs	In order to meet the gap of a very low graduate to postgraduate pharmaceuticals education seats capacity of 1:10 (51000 graduate seats vs. 5100 PG seats in the entire country), there is need to set up further new NIPERS apart from the 6approved in the 11th plan. It is proposed to set up 10 New NIPERs in the XIIth plan
(ii)	New Schemes at NIPER Mohali	R&DCentre for BiologicalsandNCEs, R&D Centre for NDDS , Setting up 20 New Incubators , Incentive Scheme for CROs development for new drug discovery, Partnership with International Centres of Excellence
(iii)	Pharma Venture Capital Fund	To consider investment of identified funds into a newly created specialised private equity / venture capital fund that undertakes R&D investments into companies in the pharmaceutical industry

(iv)	Pharma Innovation and Infrastructure Development Initiative (PIIDI)	Develop technical and innovation capacity of Indian pharmaceuticals for manufacturing quality affordable medicines ,develop international competitiveness of the Indian pharmaceuticals industry so as to be the largest producer of generic medicines in the world, To make India a preferred destination for global initiatives in curing the world's ailments specially the developing world in a value based manner
(v)	At NIPER Hyderabad : Setting up National Center for R&D in Bulk Drugs at NIPER Hyderabad	Build competitiveness through innovation and productivity efficiencies in the API industry. Also tap generics opportunity and meet competition of China, etc.
(vi)	At NIPER Kolkata: National Pharmaceutical Nanotechnology Center	To be set up at NIPER Kolkata for development of nano-materials from inorganic substrates for innovative drugs and drug delivery systems
(vii)	Setting up National and Regional Bio-similar Expertise Centres	To provide expert advice and assistance to industry on regulatory issues pertaining to clinical trials, testing and approval process for bio-similars – One national centre at Bangalore and 3 regional centres at Chandigarh, Hyderabad and Ahmedabad
(viii)	Setting up of an Industry focused Animal House	End to end services from Primates to small animals for pre-clinical drug development
(ix)	Support to Academia, Research Institutions and private sector for Extra Mural Research	For funding both academia individually, as an institution and private companies for targeted drug development including assistance for clinical trials.
(x)	Support to Academia, Research Institutions and private sector for Extra Labs up-gradation	For funding up-gradation of labs in the private and government sector on 50:50 sharing basis for the lab up-gradation, equipment deployed for drug development under specifically identifiable projects
(xi)	All NIPERs : International cooperation in R&D	To promote R&D in CIS and developing countries for mutual advantages
3	**Pricing**	
3.1	**Continuing schemes**	
(i)	Monitoring and Enforcement Work	Strengthening the existing monitoring and enforcement work
(ii)	Awareness and Publicity	Consumer awareness and publicity through

		print, electronic and other medium
3.2	**New Schemes**	
(i)	Creation of NPPA-State Government Coordination Cells in States	Scheme originally proposed in 11th Plan but not approved by Planning Commission. Hence proposed for 12th Plan. Will help in strengthening the monitoring objective of drugs prices.
(ii)	Scheme for Interaction with States	Scheme originally proposed in 11th Plan but not approved by Planning Commission. Hence proposed for 12th Plan. Will help in strengthening the monitoring Objective of drugs prices.

Source: Report of Working Group on Pharmaceuticals, 12th Plan, Government of India

Human Resource and Skill Development

The Government of India has established the National Institute of Pharmaceutical Education and Research (NIPER) established at Mohali, Chandigarh in 1997 followed by setting up of six National Institutes of Pharmaceuticals Education and Research (NIPER) at Rae Bareilly, Hajipur (Patna), Hyderabad, Ahmedabad, Guwahati and Kolkata. These provide post graduate and PhD level education and contribute to some 1800 Masters and PhDs per year. Other central government institutes include – The Indian Institute of Chemical Technology (IICT), Centre for Cellular and Molecular Biology (CCMB), National Institute of Nutrition (NIN), Centre for DNA Fingerprinting and Diagnostics (CDFD), Indian Immunological Ltd (IIL), etc. number of State Government Universities and Colleges also offer both graduate and post graduate education in pharmaceutical sciences. The above resources are also supplemented by the institutes and colleges in the private sector. Together both the government and private sector roll out some 51,000 graduates and 5,200 post graduates in pharma sciences every year.

Environmental concerns

A major concern in maintaining competitiveness for Indian pharmaceutical industry is the adherence to environmental standards of developed countries. The foreign companies have become very stringent on ensuring local environment standard & other compliance standards. This has led to a big challenge for the Indian pharmaceuticals industry, particularly small scale units, which cannot make huge investments in ensuring environmental compliances. The working group on Pharmaceutical sector for 12th plan has proposed a new scheme for environment standards compliance and required infrastructure support including capacity building, wherein financial and technical assistance would be provided to improve financial sustainability of SMEs and to safeguard the environment from the hazards associated with the unplanned growth of the industry.