Presentation on the Drugs & Cosmetics (Amendment) Bill-2007 for setting up of the Central Drug Authority of India

Objectives of the Bill

- Setting up of autonomous Central Drugs Authority of India (CDAI) of global standards under the Ministry of Health & FW.
- To introduce a system of centralized licensing for manufacture of drugs in pursuance of the recommendation of the Mashelkar Committee.
- Provision in the Act for grant of permission for Clinical Trials, and penal provisions.
- Other consequential changes in the Act to make it in consonance with the proposal for setting up of CDAI.

History of Indian Pharmaceutical Industry

	1947	1970	1990	2000	2006
No. of Units	100	2000	6000	9000	10000
Volume of Business					
Local	10 Crs	8000 Crs.	12000 Crs.	20000 Crs.	35000 Crs.
Export	Nil	2000 Crs.	6000 Crs.	12000 Crs.	21000 Crs.
Types / Categories of Products	Tablets., Liquids Capsules, Powders & Tinctures	APIs Vaccines	MDIs, Injectables, LVP with FFS Technology	Biotech Products Prefilled Syringes, NDDS	Biotech products, Prefilled Syringes, NDDS

History of Indian Pharmaceutical Industry

	1947	1970	1990	2000	2006
Global Recognition	No Recognition	Exports to African countries	Exports to African & Developing countries. Export of Bulk Drugs and initiation of Drug Delivery Research	Biotech Products Discovery Research, approval by Agencies like US FDA	India is a favorite destination for outsourcing for the following activities in the drug discovery, clinical trials formulation development & customer synthesis

Current Growth Rate (Percentage Per Annum)

- Local Market 10 to 12
- Exports 15 to 20
- Clinical Research 30

Functions & Powers of the Central Government

- Making Legislation
- Laying down standards for drugs, cosmetics, diagnostics and devices and updating of Indian Pharmacopoeia
- Registration & control on the quality of Imported drugs
- Clearance of New Drugs & Investigational New Drugs (IND)

Functions & Powers of the State Government

- Licensing of Manufacturing establishments and sales premises
- Carrying out inspections of licensed premises for ensuring compliance to conditions of licenses
- Drawing samples for test and monitoring the quality of drugs and cosmetics moving in the State

Continued……

- Taking appropriate actions like suspension/ cancellation of licenses
- Surveillance over sale of spurious/adulterated drugs
- Instituting legal action, wherever needed, as provided in the Act and Rules and
- To monitor objectionable advertisements pertaining to drugs

Joint Functions & Powers of Central & State Government

Approval of Licenses for the manufacture of the following drugs:

- Vaccine & Sera
- Blood Bank & Blood Products
- R-DNA Products
- Large Volume Parenterals
- Medical Devices

Inadequacies in the States Drugs Regulatory System

- Inadequacy of trained and skilled personnel and lack of technical support commensurate with the specialized role & responsibility and emerging challenges of the pharmaceutical industry
- Inadequate infrastructure in respect to Drug Testing Labs.
- Lack of performance management system
- Inadequate administrative, professional and financial support

Problems in the existing regulatory system

- Wide variations in implementation of GMP (Schedule M)
- Licensing of Fixed Dose Combinations
- Lack of uniformity in action taken against manufacturers for violations
- Lack of co-ordination between the states for furnishing information about the manufacturers
- Lack of uniformity in compliance to directions of Central Government
- lack of data base of drug products licensed by various state authorities

Globalization - Opportunities

- Contractual Manufacture
- Contractual R & D

a. Formulation Development

b. Clinical Research

c. Collaborative Clinical Trials

d. Customized Synthesis

Globalization - Opportunities

- Services
  - analytical method development and validation
  - clinical data management
- Production of ancillary equipment and materials
- Manufacture of primary and secondary packing material

Expectation of Global Pharmaceutical Industry

- Centralized Agency
- One agency and its capacity to overview all the activity related to Drug Development and manufacture
- Harmonization with global regulations
- Transparency and simplification of procedures
- On par treatment with local companies.

Mashelkar Committee (2003)

- Globally almost in all the countries the drug manufacturing licensing procedures are with the regulatory authority is centralized with whole of the country and Drug Authority reports to Ministry of Health.
- The problems in the regulatory system in the country are primarily due to :
  - Inadequate or weak drug control infrastructure at the State and Central level;
  - Inadequate testing facilities;
  - Shortage of drug inspectors;
  - Non-uniformity of enforcement;
  - Lack of specially trained cadres for specific regulatory areas;
  - Non existence of data bank; and
  - Non-availability of accurate information

Mashelkar Committee Recommendations

- Creation of Autonomous Central Drug Authority
- Centralized Licensing System
- Strengthening of the penal provisions for offences committed under Drugs & Cosmetics Act
- Strengthening of the drug administration in the country

Reasons for Creation of CDAI

- To have uniformity
- To avoid multiplicity of regulatory Agencies
- To represent globally as homogeneous single agency
- To cope up with regulatory requirements due to new technologies and new therapies
- Products manufactured in a state can be sold all over the country

Benefits to be derived with the creation of CDAI

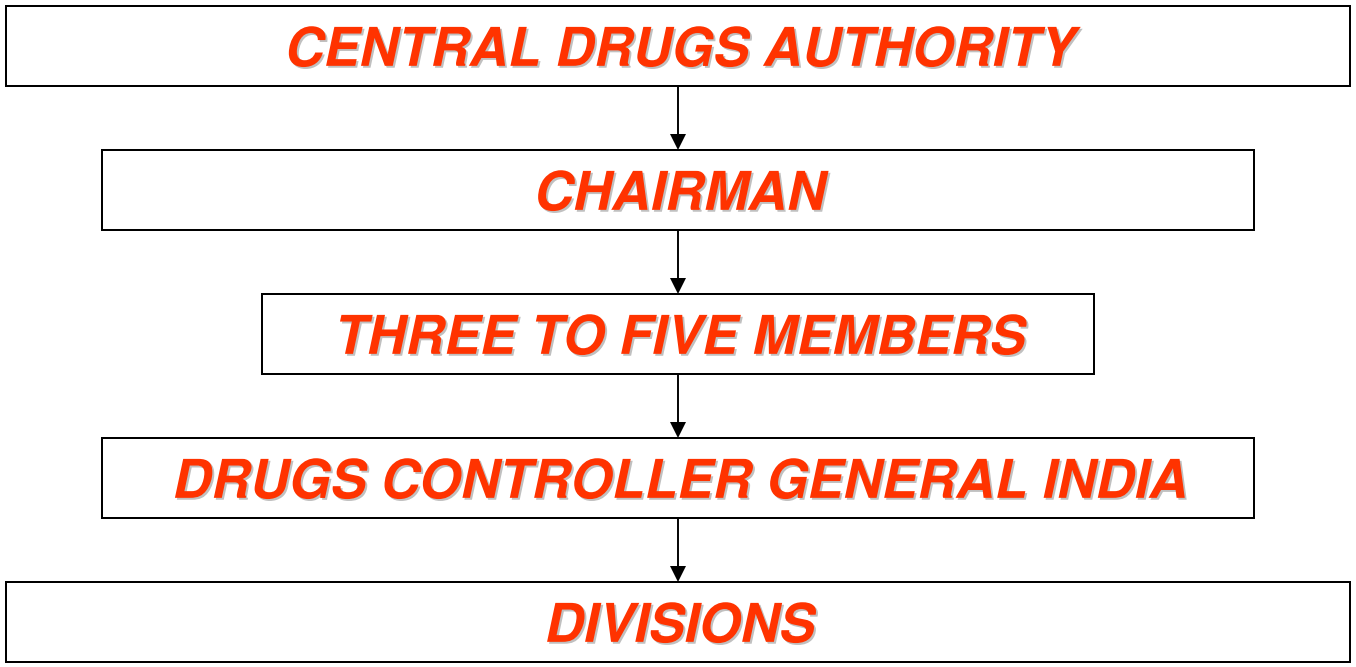
- Access to New Technologies & Therapies
- Ability to produce drugs cost effectively
- Increased and easier access to global markets
- Capacity Building in drug discovery and development
- Earning of foreign exchange
- Growth of Employment opportunities
- Growth of Ancillary industry and services

Drug Regulatory Status in Selected Countries

Countries	Title of the country's drug regulatory authority.	To whom does the head of regulatory authority report	Is Drug Regulatory Authority centralized for the whole country?	Licensing of drug mfr.
USA	FDA Commissioner	Secretary of Health	Central	Central
CANADA	Director General	Deputy Minister	Central	--
BRAZIL	President Director	Ministry / Deptt. of Health	Central/State	Central
AUSTRALIA	Therapeutic Good Admn. TGA – Director	Secretary of Health	Central	Central
Thailand	Director – Thai Food & Drugs Admn.	Ministry / Deptt.of Health	Central	Central

Continued……..

Countries	Title of the country's drug regulatory authority	To whom does the head of regulatory authority report	Is DRA centralized for the whole country?	Licensing of drug mfr.
Malaysia	Director, Drugs Control Authority	DGHS	Central	Central
China	Director, SDA	Vice Premier who is responsible for Health, Food & Drugs	Central	Central
South Korea	Director-Korea Food & Drugs Admn.	Min/Deppt. of Health (President National assembly)	Central/State	Central
South Africa	Registrar – medicines Control Council which is an independent body appointed by the MH	DGHS	Central	----
India	DCG(I) at Center and SDCs at States	DGHS	Central/State	State



1. Regulatory Affairs & Enforcement
2. Import
3. New Drugs & Clinical Trials Enforcement
4. Biologicals & Bio-technology Product
5) Pharmacovigilance
6) Medical Devices & Diagnostics
7) Organizational Services
8) Training & Services
9) Quality Control Affairs
10) Legal & Consumer Affairs

Functions of the CDAI

- Licensing of drug manufacturing units
- Registration of drugs imported in to the country
- Quality control of imported drugs
- Post marketing surveillance
- Control on medical devices
- Control on diagnostics
- Control on neutraceuticals, feed supplements and herbal products

Continued…..

- Guidelines for promotional literature
- Promotion of rational use of drugs
- Guidelines for self medication
- Monitoring of clinical trials and bio equivalence studies.
- Monitoring of ADRs
- Interaction with consumers and handling of complaints
- Central nodal intelligence cum legal cell to coordinate the interstate activities
- Training of regulatory and laboratory personnel

AYUSH (Drugs Consultative Committee)

- The proposed Act provides for an advisory committee called the Ayurvedic, Unani & Sidda (Drugs Consultative Committee) to advise Government and Central Drugs Authority of India (CDAI).
- The committee shall consists of representatives of Central & State Govts., Industry, Consumer Associations, Academic and Research Institutes.
- The composition of the committee would ensure participation of the various stakeholders in decision making process of the proposed CDAI.

Other New Initiatives

In order to improve/ strengthen the oversight role of Government through improved drug regulation & address safety concerns the following initiatives are being taken

- Amendment to Drug & Cosmetics Act to incorporate more stringent, penal provisions (clinical trials would be controlled)
- Setting up of Indian Pharmacopoeia Commission – for increased reference standard and regular publication of Indian Pharmacopoeia
- Monitoring the adverse drug reaction under the National Pharmacovigilance Programme.

Areas of Concern in Drugs

- Increasing concern for consumer protection from unsafe and poor quality of drugs, while there are regulations for quality assurance, enforcement is weak and outdated.

- Need for investment for good infrastructure in the country to ensure the quality of drugs.

- Improved drug regulation and safety would contribute to increased confidence in Indian products, making them more competitive for exports in the global market.

- The problems being faced by the sector are such as limited institutional capacities, inadequate laboratory infrastructure resulting in incomplete testing and delayed reporting.

Objective of the Capacity Building Project

- Achieving uniform GMP and GLP and better enforcement of the D&C Act and Rules uniformly throughout the country.

- Enhance capacities in laboratories at Central and States level through infrastructure strengthening and training of personnel.

- Strengthening surveillance systems for adverse drug events.

- Setting up of the Indian Pharmacopoeia Commission for preparation, printing and distribution of National Formulary of India.

PROJECT COST

The project is estimated to cost Rs.325.37 crs.
Physical and Price contingencies of Rs. 29.28 crs.
Total Project Cost Rs.354.65 crs.

(Figures: Rs. in Crores)

Name of the Component	Total (In Indian Rupees)
A. Food Safety	214.52
B. Quality Control of Drugs	**110.85**
Total (A + B)	**325.37**
C. Contingency	29.28
Total Project Cost (A + B + C)	**354.65**
D. World Bank Funding	236.38
E. Government of India Funding	88.99

This five year Central Sector Project became effective in October, 2003

Project Coverage

A. Central Sector:

- 3 Drug Laboratories in the Central Sector have been covered under the project. The details of the laboratories covered in the Central and the State Sector are as under. State wise extent of coverage is indicated below:-

1. Central Drug Testing Laboratory, Chandigarh
2. Regional Drug Testing Laboratory, Guwahati
3. Indian Pharmacopoeia Commission, Ghaziabad

Project Coverage

B. State Sector:

23 Drugs Laboratories all over the country have been covered under the project. State wise extent of the coverage is indicated below:

STATES	DRUG SECTOR
Andhra Pradesh	1. Drug control laboratory, Hyderabad 2. Drug control laboratory, Vizag
Bihar	Drug Laboratory, Patna
Chattisgarh	Drug Laboratory, Raipur

Project Coverage

STATES	DRUG SECTOR
Delhi	Drug Laboratory
Gujarat	Drug Laboratory, Baroda
Goa	Drugs Laboratory , Panaji
Haryana	State Drug Testing Laboratory
Himachal Pradesh	State Drug Laboratory
Jammu & Kashmir	1. State Drug Laboratory, Jammu 2. Drug Testing Laboratory, Srinagar
Jharkhand	Drug laboratory, Ranchi
Karnataka	State Drug Laboratory
Pondicherry	State Drug Laboratory
Rajasthan	Drugs Testing Laboratory
Tripura	State Drug Laboratory, Agartala
West Bengal	Drugs Laboratory , Kolkata
Madhya Pradesh	Drugs Laboratory, Bhopal
Maharashtra	1.Drug Control Laboratory, Mumbai, 2.Drug control laboratory, Aurangabad
Meghalaya	Drug Testing Laboratory, Shillong
Nagaland	Drug Control Laboratory, Kohima
Uttar Pradesh	State Drug Laboratory, Lucknow
Uttaranchal	Drug Laboratory

Project Components

- Civil Works
- Provision for Equipments
- Manpower
- Training for Drug Regulatory Staff & Industry Personnel

Drugs Training

- NIPER retained as training institute for training of drug regulatory staff and industry personnel
- Details of training conducted by NIPER from Jan 2004 till date

Sr. No	Training Program	No. of Programmes held	Targeted Participants as per PIP	Participants Attended
1.	Drug Regulatory Personnel	6	210	241
2.	Production Staff from SSI	11	500	644
3.	Analytical Staff from SSI	9	450	454
4.	Staff from Private Testing Laboratories	4	105	142
5.	Staff from Government Testing Laboratories	6	175	284
	Total	**36**	**1440**	**1765**


THANK YOU