REPORT ON THE DRUGS AND PHARMACEUTICALS SECTOR

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1. Introduction

India enjoys a significant global position in pharmaceutical sector. According to a sector analysis by Equite Master Indian Pharmaceutical industry the Indian Pharmaceuticals market is the 3rd largest volume wise (10%) and the13th largest (1.4%) value wise globally. India is the largest exporter of generic drugs globally which account to 20%. Of the total export of drugs, 55% constitutes formulation and 45 per cent constitute bulk drugs. The total retail medicine market in India is worth Rs 45,000- Rs 50,000-Cr (New India Express 2014). According to McKinsey report on Pharma 2020 the Indian India's pharmaceutical sector is poised to grow to US $ 55 billion by 2020 (McKinsey 2015).

According to Ministry of External Affairs update on the sector in 2015, India has the maximum US Food and Drugs Administration registered manufacturing units which stood at 523 by March 2014. This has given a competitive edge for the Indian pharmaceutical sector globally. This will also help Indian which is currently eyeing to capture Japanese market which has currently opened up the import of medicine to cater to its ageing population and higher cost of health care. The per capita consumption of drugs in India, stands at US$3, is amongst the lowest in the world, as compared to Japan- US$412, Germany- US$222 and USA- US$191(McKinsy 2015).

The Indian Pharmaceutical Industry is one of fastest emerging international Center for Contract Research and Manufacturing services (CRAMS). The main factors for the growth of the CRAMS are due to the international standard quality and low cost. The estimated value of the CRAMS market in 2006 was US$ 895 million (Business Maps of India 2015).

According to a report by economic times pharmaceutical sector employed around 4,50,000 people in 2013.

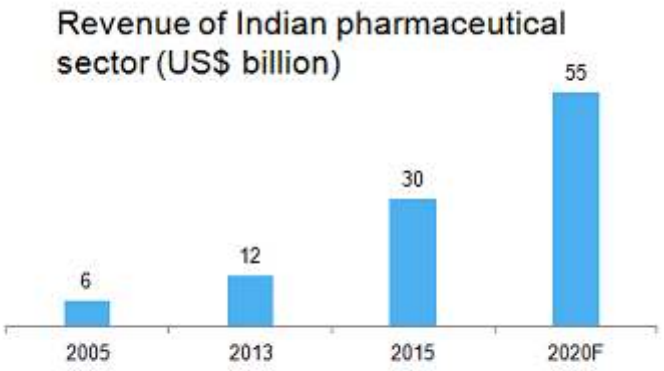
1.1 Definition of the sector

As per the Drugs and Cosmetics rules, 1945 (last updated in April, 2003) the term “drug” includes- (i) all medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes; (ii) such substances (other than food) intended to affect the structure or any function of human body or intended to be used for the destruction of 6 (vermin) or insects which cause disease in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette;) 2, iii) all substances intended for use as components of a drug including empty gelatin capsules; and (iv) such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette, after consultation with the Board.

1.2 Drugs & Pharmaceutical Sector in India

As per IBEF Indian Biotechnology industry, which is the largest sub-sector, is also expected to grow at an average growth rate of around 30% a year to reach US$100 billion by 2025 (IBEF 2016). (Annual Report 2014-15

Department of Pharmaceutical, GOI). India has a total of 24,000 pharmaceutical companies, out of which only 250 are organised. This 250 organised companies control 70% of the Indian market.



Source: Department of Pharmaceuticals, PwC, McKinsey, TechSci Research
Notes: F - Forecast, CAGR - Compound Annual Growth Rate

Indian drugs are exported to more than 200 countries in the world, with the US as the key market. Generic drugs account for 20 per cent of global exports in terms of volume, making the country the largest provider of generic medicines globally.

The Government of India plans to set up a US$ 640 million venture capital fund to boost drug discovery and strengthen pharmaceutical infrastructure. The 'Pharma Vision 2020' by the government's Department of Pharmaceuticals aims to make India a major hub for end-to-end drug discovery.

1.3 MAJOR PLAYERS

As of 2014 India has a total of 24,000 pharmaceutical companies, of which around 250 fall under the organised category. These 250 organised units control nearly 70 per cent of the market. About 8,000 small scale units together form the core of the pharmaceutical industry in India, including 5 Central Public Sector Units. About 75% of the top 20 pharma companies are Indian owned.

Figure 2: Sales Turnover of top 10 pharmaceutical companies as of 2014

1.4 SMEs IN PHARMACEUTICAL SECTOR

SMEs play crucial roles in Indian pharmaceutical company. According toIndia Micro, Small and Medium Enterprise Report 2013 the Indian pharmaceutical industry is highly fragmented and estimated to have 9,456 units in the SME segment, which account for around 87 per cent in production by volume and 40 per cent by value."

In India, SMEs are mainly focus on manufacturing and niche marketing like Contract Research and Manufacturing (CRAMs) and Bio-pharma. A report by Asia Net India states that it is recognised that the MSME units can effectively meet the two major public expectations viz. cost effective and affordable medicines of given framework of excellent manufacturing process, technology, regulatory compliance, distribution system and prices (Asia Net India2015).

1.5 FOREIGN DIRECT INVESTMENT IN PHARMACEUTICAL SECTOR

Foreign Direct Investment (FDI) up to 100% has been in operation in Pharmaceutical Sector since 2001. However, after the acquisitions of some of the major Indian Pharma Companies like Ranbaxy and Piramal, Department of Industrial Policy & Promotion in November, 2011 revised the FDI Policy.

At present 100% FDI in pharmaceutical sector is allowed through automatic route for greenfield investment. In brownfield investment, FDI is permissible Government approval route. Further in brownfield investment 'non-compete' clause is not allowed except in special circumstances with the approval of the Foreign Investment Promotion Board (FIPB). Also, FDI up to 100% through automatic route for manufacturing of medical devices has been allowed.

According to the Fact Sheet on Foreign Direct Investment (FDI) published by Department of Industrial Policy and Promotion (DIPP) in 2015, drugs and pharmaceutical sector attracted cumulative FDI inflows of US$ 12,901 million between April 2000 and February 2015.

As per Indian Brand Equity Forum (IBEF 2015) some of the major investments in the Indian pharmaceutical sector are as follows:

- Cipla announced the acquisition of two US-based companies, InvaGen Pharmaceuticals Inc. and Exelan Pharmaceuticals Inc., for US$ 550 million.
- Glaxosmithkline Pharmaceuticals has started work on its largest greenfield tablet manufacturing facility in Vemgal in Kolar district, Karnataka, with an estimated investment of Rs 1,000 crore (US$ 150 million).
- Lupin has acquired two US based pharmaceutical firms, Gavis Pharmaceuticals LLC and Novel Laboratories Inc, in a deal worth at US$ 880 million.
- Several online pharmacy retailers like PharmEasy, Netmeds, Orbimed, are attracting investments from several investors, due to double digit growth in the Rs 97,000 crore (US$ 14.8 billion) Indian pharmacy market.

- StelisBiopharma announced the breakthrough construction of its customised, multi-product, biopharmaceutical manufacturing facility at Bio-Xcell Biotechnology Park in Nusajaya, Johor, Malaysia's park and ecosystem for industrial and healthcare biotechnology at a total project investment amount of US$ 60 million.

- Strides Arcolab entered into a licensing agreement with US-based Gilead Sciences Inc to manufacture and distribute the latter's cost-efficient TenofovirAlafenamide (TAF) product to treat HIV patients in developing countries. The licence to manufacture Gilead's low-cost drug extends to 112 countries.

- CDC, the UK's development finance institution, invested US$ 48 million in NarayanaHrudayalaya hospitals, a multi-speciality healthcare provider, with an aim to expand affordable treatment in eastern, central and western India.

- Cadila Healthcare Ltd announced the launch of a biosimilar for Adalimumab - for rheumatoid arthritis and other auto immune disorders. The drug will be marketed under the brand name Exemptia at one-fifth of the price for the branded version-Humira. Cadila'sbiosimilar is the first in class and an exact replica of the original in terms of safety, purity and potency of the product, claims the company.

- Torrent Pharmaceuticals entered into an exclusive licensing agreement with Reliance Life Sciences for marketing three biosimilars in India — Rituximab, Adalimumab and Cetuximab.

- Indian Immunologicals Ltd plans to set up a new vaccine manufacturing facility in Pondicherry with an investment of Rs 300 crore (US$ 45 million).

- SRF Ltd has acquired Global DuPont Dymel, the pharmaceutical propellant business of DuPont, for US$ 20 million.

- Intas Pharmaceuticals is the first global company to launch a biosimilar version of Lucentis, the world's largest selling drug for treatment of degenerative eye condition called Razumab.

1.6 GOVERNMENT OF INDIA INITIATIVES TO BOOT PHARMACEUTICAL SECTOR

The Addendum 2015 of the Indian Pharmacopoeia (IP) 2014, published by the Indian Pharmacopoeia Commission (IPC) on behalf of the Ministry of Health & Family Welfare, is expected to play a significant role in enhancing the quality of medicines that would in turn promote public health and accelerate the growth and development of pharmaceutical sector.

1) The 'Pharma Vision 2020' by Government of India envisions to India a global leader in end-to-end drug manufacture.

2) Make in India' programme will encourage bulk drug manufacturing and reduce dependency on import of active pharmaceutical ingredients (API).

3) To deal with issues of affordability and availability of medicine the Government of India has introduced mechanisms such as the Drug Price Control Order and the National Pharmaceutical Pricing Authority.

4) The Department of Pharmaceuticals has set up an inter-ministerial co-ordination committee, which would periodically review, coordinate and facilitate the resolution of the issues and constraints faced by the Indian pharmaceutical companies.

5) To support start-ups the Department of Pharmaceuticals has planned to launch a venture capital fund of Rs 1,000 crore (US$ 154 million)

6) India plans to set up six pharmaceutical parks will be approved and established this year which will have sufficient infrastructure and facilities for testing and treatment of drugs and also for imparting training to industry professionals (IBEF 2015).

2. POLICY INITIATIVES PLANNED FOR THE PHARMACEUTICAL SECTOR

As per the Central Drug Standard Control Organization (CDSCO) of India the following policy measure were planned in 2015.

2.1 POLICY REFORMS

2.1.1 Amendments in the Act and Rules

1) Introduction of the Drugs and Cosmetics (Amendment) Bill to amend the Drugs and Cosmetics Act, 1940 for upgradation and introduction of provisions for clinical trials and regulation of medical devices.

2) Amendments in the Drugs and Cosmetics Rules, 1945 in the light of new provisions to be incorporated under the Drugs and Cosmetics Act, 1940 and strengthening of rules relating to quality control of drugs, cosmetics and medical devices.

3) Introduction of provisions relating to Phytopharmaceutical drugs under the system of modern medicine.

4) Simplification and rationalization of various formats of applications and licenses under the Drugs and Cosmetics Rules, 1945.

5) Revision of Good Manufacturing Practices for drugs as well as medical devices under the Drugs and Cosmetics Rules, 1945 to update the requirements to make them at par with the International requirements.

2.1.2 Drugs and Magic Remedies (Objectionable advertisement) Act, 1954

Review of the Drugs and Magic Remedies (Objectionable advertisement) Act, 1954 and propose amendments in the Act, wherever required.

2.1.3 Harmonization of recruitment rules

Harmonization of various recruitment rules for post in CDSCO and Central Drug Testing Laboratories.

2.1.4 E-governance

1) IT-enabled system for online submission of Clinical Trial applications is being put in place in CDSCO through NIC.

2) A plan for Digitalization of various activities of CDSCO as per recommendations of Cabinet Secretariat has been initiated.

3) Publication of revised National List of Essential Medicines as NLEM, 2015.

4) Finalization of Accreditation Standards for Clinical Trials for Ethics Committee, Investigator and Clinical Trials.

5) Evolving of Public Private Partnership model for engaging laboratories in private sector.

6) Setting up of training institutes in the existing premises of National Institute of Biologicals, Noida. (http://www.cdsco.nic.in/forms/list.aspx?lid=2014&Id=1)

3. OVERVIEW OF PHARMACEUTICAL INDUSTRY IN SOUTHERN INDIA

3.1 Karnataka

Karnataka has emerged as a centre for generics, medical devices, biotech and drug discovery. The industry is growing at 17.82 percent. In 2006-07 it accounted for 55% of the total Biotech companies in India (Financial Express). The state pharmaceutical industry constitutes 1000 pharmaceutical manufacturing units in Karnataka, out of which only a handful of units are under organised. The sector provides around 25,000 direct employments and generates Rs. 12,000 crore worth revenues. Total export revenue constitutes to Rs. 5,000 crore is from exports. It is. It is also expecting the clearance for the formation of the Karnataka Pharmaceutical Development Council (KPDC) with a budgetary provision of Rs. 1 crore and the Vision Group on Pharmaceuticals with an Rs.25 lakh allocation, which are two monitoring agencies for the development of the sector.

Table 1: Number of Drug Manufacturers in the State

Particulars	**2011-12 (31-03-2012)**
Regular license	230
Loan Licenses	272
Cosmetic Licenses	59
Cosmetic Loan Licenses	24
Re packing Licenses	5
Approved Laboratories	15
Blood Banks	176
Blood Storage Centers	103
Number of Sales premises in the State	26658

Source: Drug Control Department, Karnataka

3.2 Tamil Nadu

Tamil Nadu Drugs & Pharmaceutical sector is estimated at Rs 1500 crores per year including exports and domestic. It consumes about 8% of the domestic drug consumption of total Indian market which is

approximately Rs.4800 crores per year. Tamil Nadu is emerging as an export hub for pharma with nearly Rs. 4000 crore worth of pharma product be export to different countries from the state (Deccan Chronicle 2015).

Though there is a huge domestic market in the state, the industry is only able to produce Rs. 1200 crores worth drugs.

3.3 Kerala

It is reported that Kerala having 3% of the population of the country consumes more than 10% of drugs marketed in the country (Kerala Drug Control Department 2015).The retail market for Allopathic Medicine in Kerala is projected at Rs. 4,000 to 5,000 crores accounts to 8.8% of the total Indian drug retail market (New India Express 2016).

Kerala gives a major thrust on Ayurvedic medicinesThe state drugs control department was bifurcated into two separate wings, one for Allopathy and the other for Ayurvedain 2008 (Pharmabiz 2011). It wants to achieve Rs 5,000 crore turnover from ayurveda by 2020.The present annual revenue from the sector stood at Rs 1,000 crore (Business Standard 2014).

Kerala has formulated AYUSH Health Policy 2016, which envisages tapping the potential of the traditional systems of medicines like Ayurveda, Yoga-naturopathy, Unani and Siddha and integrating them to improve the primary and preventive health care system of the state.

With the exponential growth of new and conventional Ayurveda drugs there has been a great demand for separate Drugs Controller for Ayurveda (New India Express 2015)

Table 2

State-wise distribution of manufacturing units with WHO-GMP certification	
State	**No of units**
	Total no. of WHO GMP Certified Manufacturers
Kerala	10
Karnataka	82
Tamil Nadu	75
Total	**167**
Total (India)	**1330**

Source: Central Drugs Standard Control Organisation (CDSCO)

4. OVERVIEW OF DRUGS REGULATION IN INDIA

Drugs regulatory structure is divided between national and state authorities India. The main functions of the Central and State Government are as given in the table.

Table 3: The main functions of the Central and State Government

CENTRAL GOVERNMENT	STATE GOVERNMENTS
Statutory Functions	Statutory Functions
Laying down standards of drugs, cosmetics, diagnostics and devices.	Licensing of drug manufacturing and sales establishments
Laying down regulatory measures, amendments to Acts and Rules.	Licensing of drug testing laboratories
To regulate market authorization of new drugs	Approval of drug formulations for manufacture
To regulate clinical research in India	Monitoring of quality of Drugs & Cosmetics, manufactured by respective state units and those marketed in the state
To approve licenses to manufacture certain categories of drugs as Central License Approving Authority i.e. for Blood Banks, Large Volume Parenterals and Vaccines & Sera.	Investigation and prosecution in respect of contravention of legal provisions
To regulate the standards of imported drugs.	Administrative actions
Work relating to the Drugs Technical Advisory Board(DTAB) and Drugs Consultative Committee (DCC)	Pre- and post- licensing inspection.
Testing of drugs by Central Drugs Labs.	Recall of sub-standard drugs
Publication of Indian Pharmacopoeia.	

In India Drugs classified under 5 heads or Schedules. They are

a) Schedule X drugs – Narcotics
b) Schedule H and L – Injectables, Antibiotics, Antibacterial
c) Schedule C and C1- Biological Products-example Serums and Vaccines

Currently the manufacture, sale, import, exports and clinical research of drugs and cosmetics is governed by the following laws:-

a) The Drugs and Cosmetics Act, 1940

b) The Pharmacy Act, 1948

c) The Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954

d) The Narcotic Drugs and Psychotropic Substances Act, 1985

e) The Medicinal and Toilet Preparations (Excise Duties) Act, 1956

f) The Drugs (Prices Control) Order 1995 (under the Essential Commodities Act.

4.1 Drug & Cosmetic Act, 1940

"Chopra Committee" recommended among others, to make Central Legislation to Control drugs. As a result, The Drugs and Cosmetic Act was enacted in 1940 under the British Rule. The Government of India passed the “Drugs Act” in 1940 to regulate the import, manufacture, distribution and sale of drugs. The Drugs Act came into being on 10th April 1940. The Drugs Rules were framed during 1945 to give effect to the provisions of the Act.

This central legislation regulates India's drug and cosmetic import, manufacture, distribution and sale. This established the Central Drugs Standard Control Organization (CDSCO), and the office of its leader, the Drugs Controller General (India)(DCG (I).

4.2 Pharmacy Act,1948

Pharmacy Act was enacted in 1948 to regulated the profession and practice of pharmacy in India. The Act has led to the institution of the Pharmacy Council of India (PCI) which regulates the functioning of pharmacy education institutions. PCI acts through state pharmacy councils. PCI is also the statutory body to register pharmacy graduates.

4.3 Drugs & Magic Remedies (Objectionable Advertisements) Act 1954

Constituted in 1954 the Drugs and Magic Remedies Act talks about controlling the advertisement of drugs in certain cases, to prohibit the advertisement for certain purposes of remedies alleged to possess magic qualities and to provide for matters connected there with. State drug regulators are the enforcement agencies of D &MR Act.

4.4 Some Other Laws

There are some other laws which have a bearing on pharmaceutical manufacture, distribution and sale in India. The important ones being:

a) The Industries (Development and Regulation) Act, 1951

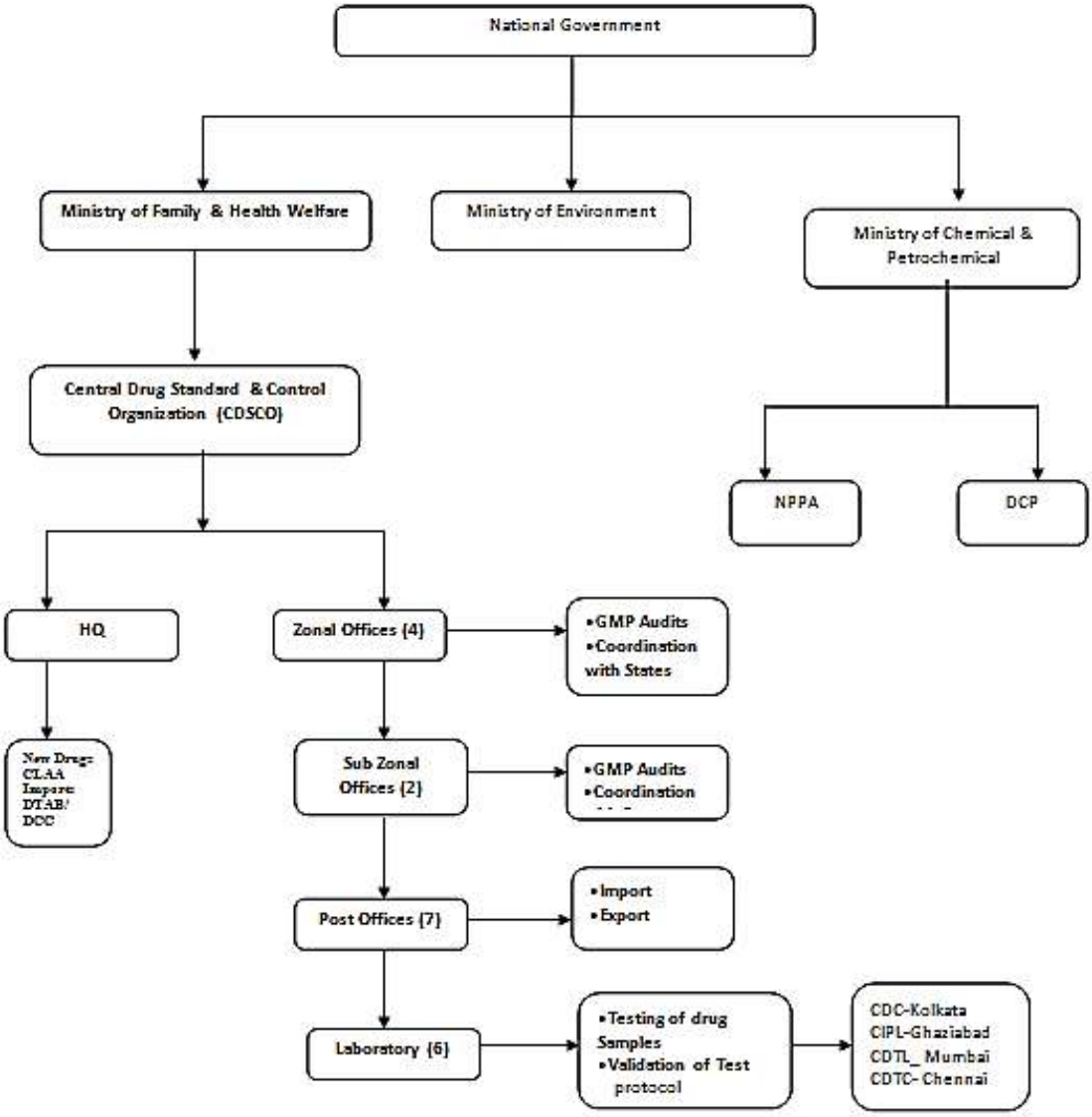
b) The Trade and Merchandise Marks Act, 1958

c) The Indian Patent and Design Act, 1970

d) Factories Act

4.5 Drug Regulatory Structure in India

Figure 3 Drug Regulatory Structure



Source: Central Drugs Standard Control Organisation (CDSCO)

Indian Drugs and Pharmaceutical sector is regulated by CDSCO - Central Drugs Standard Control Organization under Ministry of Health and Family Welfare. Headed by Directorate General of Health Services CDSCO regulates the Pharmaceutical Products through DCGI - Drugs Controller General of India.The DCGI registers all imported drugs, new drugs, and drugs in selected categories. It also has responsibility for clinical trials and quality standards.

The state FDA's register all other products, accredit manufacturing plants, and conduct the bulk of quality monitoring and inspections.

4.5.1 Functions of CDSCO:

a) Approval of new drugs and clinical trials

b) Import Registration and Licensing

c) Licensing of Blood Banks, LVP's, Vaccines, r-DNA products & some Medical Devices

d) Amendment to D &C Act and Rules

e) Banning of drugs and cosmetics

f) Grant of Test License

g) Personal License

h) NOCs for Export

i) Testing of Drugs

4.5.2 Functions of Central Drugs Laboratory (CDL)

a) The functions of the Laboratory include: Statutory Functions: Analytical quality control of majority of the imported Drug available in Indian market.

b) Analytical quality control of drug and cosmetics manufactured within the country on behalf of the Central and State Drug Controller Administrations.

c) Acting as an Appellate authority in matters of disputes relating to quality of Drug.

Other Functions:

a) Collection, storage and distribution of International Standard International Reference Preparations of Drug and Pharmaceutical Substances.

b) Preparation of National Reference Standards and maintenance of such Standards. Maintenance of microbial cultures useful in drug analysis Distribution of Standards and cultures to State Quality Control Laboratories and drug manufacturing establishments.

c) Training of Drug Analysts deputed by State Drug Control Laboratories and other Institutions.

d) Training of World Health Organization Fellows from abroad on modern methods of Drug Analysis.

e) To advise the Central Drug Control Administration in respect of quality and toxicity of drug waiting license.

f) To work out analytical specifications for preparation of Monographs for the Indian Pharmacopoeia and the Homoeopathic Pharmacopoeia of India.

g) To undertake analytical research on standardization and methodology of Drug and cosmetics.

h) Analysis of Cosmetics received as survey samples from Central Drug Standard Control Organization.

i) Quick analysis of life saving Drug on an All-India basis received under National Survey of Quality of Essential Drug Programme from Zonal Offices of Central Drug Standard Control Organization.

4.6 Indian Pharmacopoeial Commission (IPC)

Indian Pharmacopoeial Commission is an Autonomous Institution under the Ministry of Health & Family Welfare, Govt. of India dedicated for setting of standards for drugs, pharmaceuticals and healthcare devices/ technologies etc besides providing Reference Substances and Training.

4.7 New Drug Approval

Medicinal products count as 'new drugs' in India if they fall into one of the following categories:

a) Drugs not previously available on the market in India l

b) Drugs with new therapeutic indications or dosages that have not been marketed in India

c) New fixed-dose combinations of two or more drugs

d) Any drug which was first approved in India less than four years ago, unless it is included in the Indian Pharmacopoeia

e) All vaccines are treated as new drugs, unless notified otherwise by the DCGI.

f) Guidance document on Common Submission Format for Import and Registration of bulk drugs and finished formulations in India:

4.8 Investigational New Drug Application

4.8.1 Types Of Ind Application In India

CATEGORY- A

These includes clinical trials whose protocols have been approved by USA, UK, Switzerland, MEA, Japan, Australia, Canada, Germany, South Africa. These are also known as Abbreviated INDs. Category-A applications are approved within 3-4 weeks of filling.

CATEGORY- B

All other clinical trials not Covered under category-A will fall under Category-B, and will be reviewed normally defined earlier. Most phase-1 clinical trials are reviewed as Category-B applications. Category-B applications are approved within 8-12 weeks.

4.9 Clinical Trial Requirements

4.9.1 Phases Of Clinical Trials

- PHASE-1 TRIALS (Human Pharmacology)- To determine safety and tolerability of a drug. Common objectives are to determine MTD, ADME and MOA of the drug.
- PHASE-2 TRIALS (Therapeutic Explanatory Trials)- To determine the effectiveness and safety of the drug for a particular indication.
- PHASE-3 TRIALS (Therapeutic Confirmatory Trials)- To confirm the therapeutic benefits of the drug. The results must support the prescribing information.
- PHASE-4 TRIALS (Post Marketing Trials)- To compare the risk and benefits of the drug in wider population after the approval of the drug.

4.9.2 Major Mile Stones in Clinical Trials in India

August 2013: Drugs and Cosmetics (Amendment) Bill 2013 introduced in Parliament, which contains penal provisions for violations of clinical trial procedures, and provisions for payment of compensation and ethics committees.

August 2013: The DCGI makes it mandatory for the sponsor or his representatives to furnish the details of the contract between the sponsor and the investigator with regard to financial support, fees, honorarium, and payments in kind to be paid to the investigator.

September 2013: India's Supreme Court suspends all clinical trials of new drugs in the country.

September 2013: Contract research organization Quintiles closes its research centre in Hyderabad, a joint venture with Apollo Hospitals Enterprise.

November 2013: The DCGI issues a directive that an audiovisual recording of the process of obtaining written informed consent is required for each trial subject.

January 2015: The health ministry proposes pre-submission meetings in a bid to enable technical deliberations between stakeholders and the drug regulator before clinical trial applications are submitted.

4.9.3 Regulation & Approval Of Clinical Trials

No new drug clinical trial can be carried out without the permission of the DCGI, and the approval obtained from the respective ethics committee(s). Trial sites and the protocol must be approved by independent ethics committee (s). Important regulations are-

- SCHEDULE-Y Amended Version 2005.
- GCP Guidelines as per CDSCO.
- ICMR Guidelines, 2006. (Revised)
- GLP Guidelines as per CDSCO.
- BIOAVAILABILTY & BIOEQUIVALANCE Guidance.
- National Pharmacovigilance Programme, 2004.

5 REGULATORY FRAMEWORK IN THE STATES

At the state level Drugs and Pharmaceutical sector is regulated by Drugs Control Department. It reports to the State Health and Family Welfare Ministry. In India though the sector is regulated by the Central Acts the regulatory systems at the state do not have links with the Central regulatory system.

A point to note here is that medicines cannot be introduced in the Indian market without the permission of Drug Control General of India (DCGI), but the manufacturing license is provided by the State Licensing Authority.

The State Drug Control Department came into being after the implementation of The Drugs and Cosmetics Act, 1940 and Rules, 1945.Thereafter over a period of time more number of Inspectors & Government Analysts were appointed with ancillary staff for the implementation of the Act.

The Government of India, Ministry of Health, amended the Drugs & Magic Remedies (objectionable advertisements) Act, 1954 where in the duties of search and seizure under this act were entrusted to officers holding Gazetted status only and on review of the status of Drugs Inspectors of various states, it was observed that in some states the Drugs Inspectors were gazetted and in other States they were Non- Gazetted.

The Central Council of Health at its meeting held on 5th to 7th November 1963 adopted a resolution recommending that the Drugs Inspectors of all States should be of gazetted rank and in view of this the State Government conferred Gazetted status to the Drugs Inspectors and sanctioned 20 posts of Drugs Inspectors with effect from 17/12/1966.

In 1966, the three-member committee of Government of India headed by Sri. S.K. Borkar, the then Drugs Controller (India) gave their report after study of the setup of various state Drug Control Administrations, staffing pattern and Drug Testing facilities recommending expansion of Drug Control Administrations in the states for more stringent enforcement of

- The Drugs and Cosmetics Act, 1940 and Rules, 1945.
- The Drugs and Cosmetics Act 1940 and Rules 1945
- The Drugs and Magic Remedies (Objectionable Advertisements) Act 1954 and Rules 1955
- The Narcotic Drugs and Psychotropic Substances Act, 1985 and Rules,1985
- The Drugs Price (Control) Order, 1995

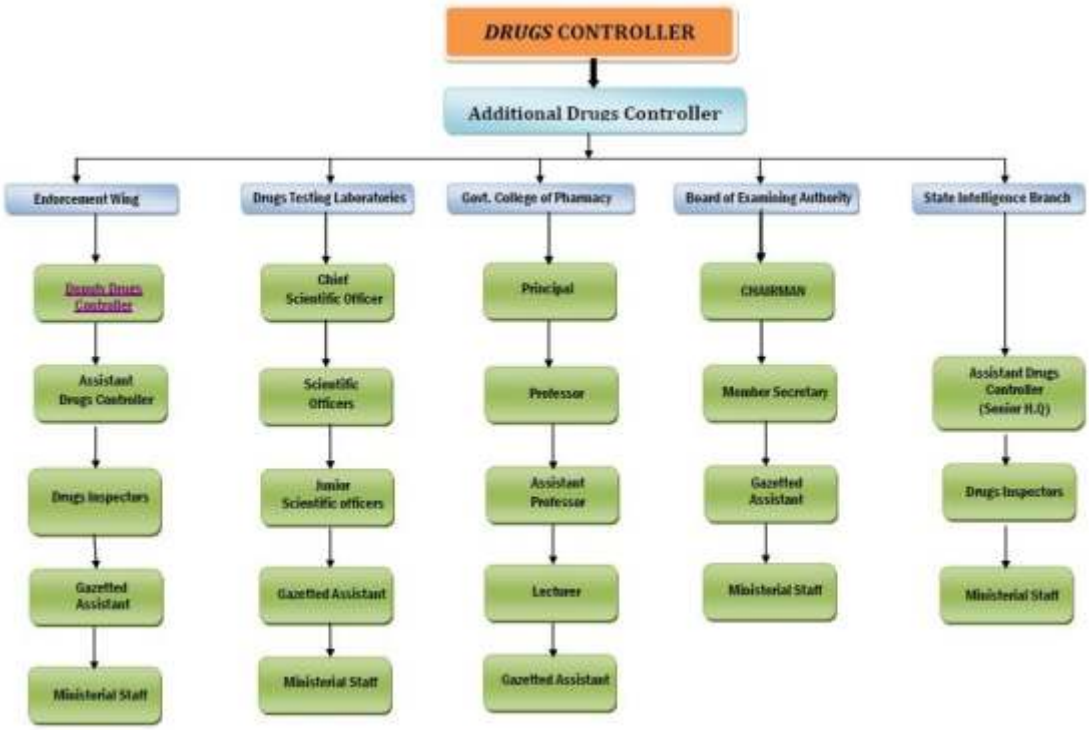
5.1 Functions of Drugs Control Department

- To grant and renew licenses for the following Categories of Drug Manufacturing Units
- Allopathic Drugs
- In Kerala a separate wing has been set up for Ayurvedic Drugs
- Blood, Blood Products
- Medical Devices
- To grant and renew licenses for Drug Selling Units
- To grant approval for Public Testing Laboratory and Blood Storage Centres
- To issue quota of Narcotics Drugs under the Narcotics Drugs and Psychotropic Substances Act

- To investigate complaints received regarding drugs
- To carry out inspections of manufacturing and selling Units
- To draw samples of Drugs
- To conduct raids for those manufacturing spurious drugs /substandard drugs
- To take legal action against the offenders and prosecute
- To give approval to personnel as Competent Technical Person for Manufacturing and Testing
- To educate the consumers for the safe use of Drugs
- To issue various Certificates for Tenders, Exports as listed below:
    i. WHO-Good Manufacturing Practices certificate: Global standard set by World Health Organisation in 1991 to ensure quality production and use of medicines.
    ii. No Conviction certificate: To ensure that the drug manufacturer or professionals are not involved in criminal activities.
    iii. Performance Certificate
    iv. Free Sale Certificate: For manufacturer to say that the medicines sold by them are compliant, safe and legally allowed to be sold.
    v. Schedule M / GMP Certificate: Given to Drug manufactures to start production.
    vi. Capacity and installation Certificate
    vii. Market standing certificate: Given for manufacturing and sale of medicine in India
    viii. Export registration certificate: Given for sale of medicine outside India
    ix. Manufacturing and Marketing certificate: Given to medicine manufacturers and

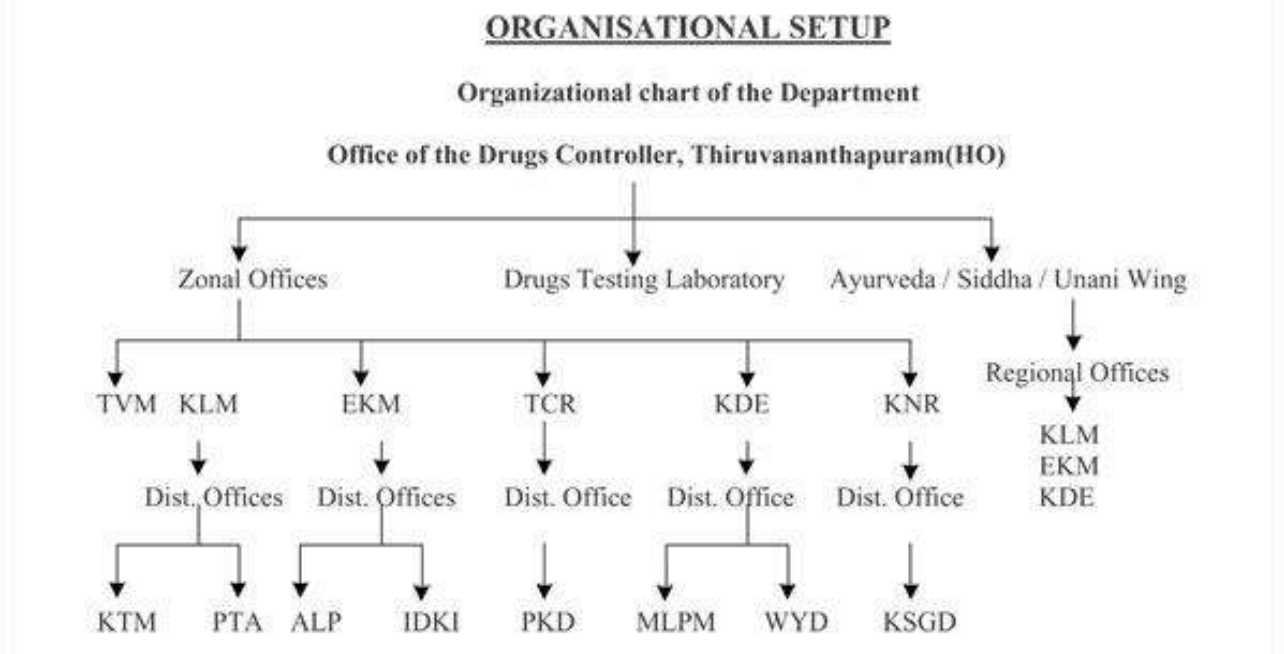
The State Drugs Control Department has the authority to cancel licenses and prosecute licensee if found guilty as per the guidelines of 40th Drugs Consultative Committee (DCC) meeting proceedings

Figure 4: Organisational Structure of Karnataka State Drug Control Department



Source: Drug Control Department, Karnataka

Figure 5: Organisational structure of Kerala Drug Control Department



Source: Drug Control Department, Kerala

6 CHALLENGES

Propelled by growth of middle class and increased health consciousness and purchasing power the Indians and demand for low cost quality medicine, the Indian pharmaceutical sector is slated to growth at double digits. However, it is often cited by the industry that the regulatory system in India are very complicated which has been acting as a deterrent to the growth of the industry. To find the issues faced by the industry Centre for Public Policy Research conducted round table discussions with the industry and government representatives in Karnataka, Tamil Nadu and Kerala. This section focuses on the outcome of the deliberation during the round table discussions.

6.1 Lack of Single Authority for regulation of Drugs and Pharma Sector

The main issues which was pointed out in all the states' round table discussions was that the apart from the usual issues of usual tedious process of getting licenses for building plan, factory licenses, obtaining NOC from Fire and Safety department, pollution control board, for setting up a company, the Industry is ladened with a plethora of compliances and gamut of regulatory Central and State ministries and department. Centre approves new drugs for the market, clinical trials, blood banks, large volume parenteral, vaccines, Sera, imported drugs, testing of drugs by central drugs labs. State provides licensing for drug manufacturers and sales establishments, approval for drug formulations for manufacturing, inspections.

There are various Ministry & departments both at the Centre and State which regulates and controls the sector. For example Pharma industry is controlled both by Centre Government and the State government Health Ministry. Drug Controller General of India DCGI reports to Central Health Ministry while the licensing authority of the state reports to State Ministry of Health. There is no coordination between the state and the Centre.

The pharmaceutical department under Chemical and Fertilizer Ministry controls the drugs pricing. However, it does not have any say in the licensing and export of the medicines.

The Export is handled by the Pharmexcil which reports to Ministry of Commerce at the Centre. Though they have plan for export promotion of the sector, but cannot contribute to the SMEs need.

The industry have to go to other Ministry like the Food Ministry for production of Dietary supplementary, obtain permission from Narcotic Department under the Home Ministry as some of the medicines are listed under narcotic. For natural and Sidha medicine the ministries and the departments differ.

The dual regulation of the state and the centre has not helped the pharma industry. At one side the companies are made to run between centre and state and at the other side the industry is inflicted with spurious and non effective medicines. It is because the though the Centre may have rejected a formulation, but the state has the power to clear them. The recent ban of 344Fixed Dose Combination (FDC) medicines with the Supreme Court support reveals this fact.

The Ranjit Roy committee's report which was to review the assigned to formulate Policies and guidelines for approval of New Drugs, Clinical Trials and Banning of Drugs in 2013 also reiterates this fact. This country has a unacceptable number of drug formulation accounting to around 60,000 to 80,000. This is due to the Centre's inability to stop this drugs coming to the market because of the reason stated earlier. Another interesting thing is that if one state rejects the production of a particular formulation another state can give approval for the same. The company can produce and market the medicine in the state which had rejected the formulation. Now all of a sudden there is a chaos in the market. The drug producers are in a fix. They say there would have a single authority to regulated and promote the sector, such a chaos would not have happened.

6.2 Land

Apart from the usual hurdles of land availability, registration and conversion of the, during the round table discussion it was found that the SMEs in the sector in Karnataka are facing a major issue in land. The Karnataka government makes it mandatory for them to make upfront payment for the land procured from it. This adds a burden to the small players.

6.3 China dumping cheap and inferior quality raw material

Due to stringent environment laws in India, 90% (as per the data from Industry & Pharmaceutical Export Promotion Council of India) of the raw material is sourced from China. India import antibiotic, penicillin and its derivations, stains, glitazones and solvents and excipients used in all formulation. There is no mechanism to check the quality of the raw material procured from China. Mostly the Chinese suppliers source raw materials from authorised manufactures. This seriously affects the quality of the medicine. US FDA has set up 4 offices in Indian and has posted 19 officials to inspect the manufacturing units that supply medicine to US. The government of India has allocated Rs. 180 crore for setting up offices in China to monitor the quality of raw materials and medical devices. But it is yet to take action.

6.4 Cumbersome Methanol Licensing in Tamil Nadu

In order to curb the illicit use of Methanol, Tamil Nadu has brought the chemical under prohibition act. However, this has brought unnecessary headaches for the pharmaceutical companies in the state. For medicine production hardly 10 liters of methanol is used annually by the companies. As per the act the companies have to provide a manned storage place and a register to need to maintained for the chemical.

They have to get special permission from the District Collected to use the chemical. Obtaining permission is not an easy process. The companies have to get NOCs from two offices i.e Excise department and the local police.

After they submit the NOCs at the collector's office the Collector or his representatives will visit the companies premise for inspection. Only after they get satisfied will they give the permission to use the chemical. The whole process is tedious and time consuming.

6.5 Lack of right to procure raw material from the forest

Due to stringent environment laws it is becoming extremely difficult to sourced raw materials from the forest. This issue was especially identified by the drugs manufacturers in Kerala. They are forced to source raw materials from North eastern region of India, which significantly increases the cost of production.

6.6 Stringent and archaic Labour Law

The labour and shop and establishment act do not allow women to work after 7 pm. This is a serious concern for the industry who often have to continue production after 7 pm. The law compels the companies to provide for conveyance and security for women workers after 7 pm. The pharmaceutical companies' employee medical representatives who call on the doctor which continues even after 7 pm.

7 RECOMMENDATIONS

1. Single Regulatory Authority: Most of the leading developed nations have single authority to promote and regulate the pharmaceutical industry. This enables them to monitor and frame policies for the industry. India should also have a Single authority. The ministry of Chemical and Fertilizer has Pharmaceutical department. This should be given more power to give licenses and promote policies for the sector. The states should not have separate power to give licenses. The State Drugs Control Board should come under the Department of Pharmaceutical at the Centre. At state level the entrepreneurs should go through the SDCB for licensing and NOC. The Pharmaceutical Department should coordinate with other ministries at the Centre to facilitate the licensing and permits. The SDCB should coordinate with the department and other state ministries and departments to better facilitation. The entrepreneurs need not go the centre for any licensing. It should be done by the SDCB.

2. Lease/rent of Land: They were of the opinion that the land in Karnataka should be given as lease or rent. This will help a long way in strengthen the small players which will in turn make them competent and competitive.

3. Quality in Import: The government should set up offices in China for ensuring quality of the raw materials. It should create an inventory of all the suppliers and inspect their facilities and sourcing. It should work with the Chinese government to ensure that the suppliers adhere to certain minimum standards of quality.

4. Exemption for Tamil Nadu manufactures from Prohibition Act: The pharmaceutical companies could be exempted from the prohibition act. This will ease them off of unnecessary time consuming.

5. Right to Collect Raw Material to Manufacturers: Some part of the forest could be allocated for sourcing raw materials. The states' forest dwellers could be made partners to the growth of pharmaceutical industry. They could be assigned and incentivised to grow, preserving and source medicinal plants and raw material required for the Industry.

6. Increase the minimum working hours: The current working hours provisions debar women from gain opportunities similar to their male counterpart. The industry is of the opinion that the working hour should be raised to 9 pm in big cities like Chennai and Banagalore.

8 CONCLUSION

Pharmaceutical industry has been performing consistency over the few decades. Cost effectiveness and quality have been to two factors which has helped the industry to go a long way. In the rapidly changing global scenario the industry will need to have withstand pressure and continue to growth at double digits. Flexible regulatory framework and monitoring process will add to the strength of the sector.

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Annexure

List of Tables and Figures