



REGULATION OF DRUGS IN ANDHRA PRADESH: A OVERVIEW***²BALAMURALIDHAR V AND ¹KEMPAIAH SURESH**

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ABSTRACT

Andhra Pradesh has been one of the pioneer States in India with an exemplary track record. The State of Andhra Pradesh has some of the country's most dynamic entrepreneurs who are original and fast-paced in their thinking and focused in their drive for growth and profitability. Drugs Control Administration regulates the manufacture, sale and distribution of drugs to ensure their quality and efficacy. Accounting for 16 percent of the country's total industrial output and 18 percent of the country's total investment, Andhra Pradesh is one of the most industrialised states in the country. It has a strong base of educational institutions imparting courses in Pharmacy and some of the institutions have international repute to its credit. Andhra Pradesh is one of the fastest growing states in the Country and nearly 500 pharma and biotech companies are housed in the State. Andhra Pradesh is a vibrant pharmaceutical manufacturing hub for Bulk Drugs. The State has knowledge based institutions and skilled human resource in the state.. In this the author has made some observations in field of pharmacy and the Regulation of Drugs in Andhra Pradesh.

KEYWORDS: *Regulation, Andhra Pradesh, Education, Health, Drug.*

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Figure 1
Andhra Pradesh

INTRODUCTION

Andhra Pradesh (AP) is India's eight largest state by area (275,045 km²) and Tenth largest by population (84,655,533 as of 2011). Hyderabad is AP's capital for ten years and largest city. The state is located on India's southeast coast and is bordered by Maharashtra, Chhattisgarh, Odisha, Tamil Nadu, and Karnataka, as well as the Bay of Bengal. The state has the second longest coastline among the other states as well as two major rivers (Godavari and Krishna). Figure 1 AP's official languages are Telugu (spoken by 84% of the population) and Urdu (spoken by 9%); other languages spoken include Hindi, Marathi, Tamil, Kannada, and Oriya. Hinduism is practiced by Factor Conditions Related and Supporting Industries Context for Firm Strategy & Rivalry Demand Conditions Highly educated workforce in engineering and sciences available at an affordable cost Major producer of agricultural commodities (cotton, tea, coffee, wheat, etc.) × Weak infrastructure (roads, rail, electricity) × Low female participation in workforce × Higher education institutions not successful at producing high quality research Largest offshore IT services industry driven by utilization of inflow of engineers Import substitution phase has provided a large availability of local suppliers Small and medium-sized enterprise sector highly entrepreneurial and extensive × Clusters in India are not effective – largely a group of isolated companies co-existing × Local suppliers tend to be of a lower quality and more price conscious Consistently strong protection for investors Post-91 liberalization of economy has encouraged further private sector participation and increased FDI in select industries Innovative capital

markets and banking. The state has a varying climate with hot summers (especially on the coastal plain) and monsoons from July to September. Following a movement for separation, it was awarded separate statehood on 2 June 2014. Hyderabad will continue to serve as the joint capital city for Andhra Pradesh and Telangana for a period of not more than ten years.¹

DRUGS CONTROL ADMINISTRATION

The Drugs Control Administration in the year 1952 was functioning in the Directorate of Medical services. The first basic level functionaries sanctioned to this Department were four Drugs Inspectors for implementation of the Drugs and Cosmetics Act, 1940 and Rules made there under (formerly called as The Drugs Act, 1940 and The Drugs Rules 1945) in the erstwhile Andhra State for implementation in Andhra area only. After the formation of separate Andhra Pradesh State in the year 1956 four more Drugs Inspectors were appointed and implementation of this Statute was extended to Telangana Area also. Subsequently, Drugs Control Administration was also entrusted with the enforcement of Prevention of Food Adulteration Act and the Head of the Department was designated as Drugs Controller and Food Health Authority. In the year 1981 the Department of Drugs Control Administration was accorded independent status with a separate Directorate headed by a Director functioning under the Ministry of Medical and Health, Government of Andhra Pradesh. Drugs Control Administration regulates the manufacture, sale and distribution of drugs to ensure their quality and efficacy. (Figure 2)

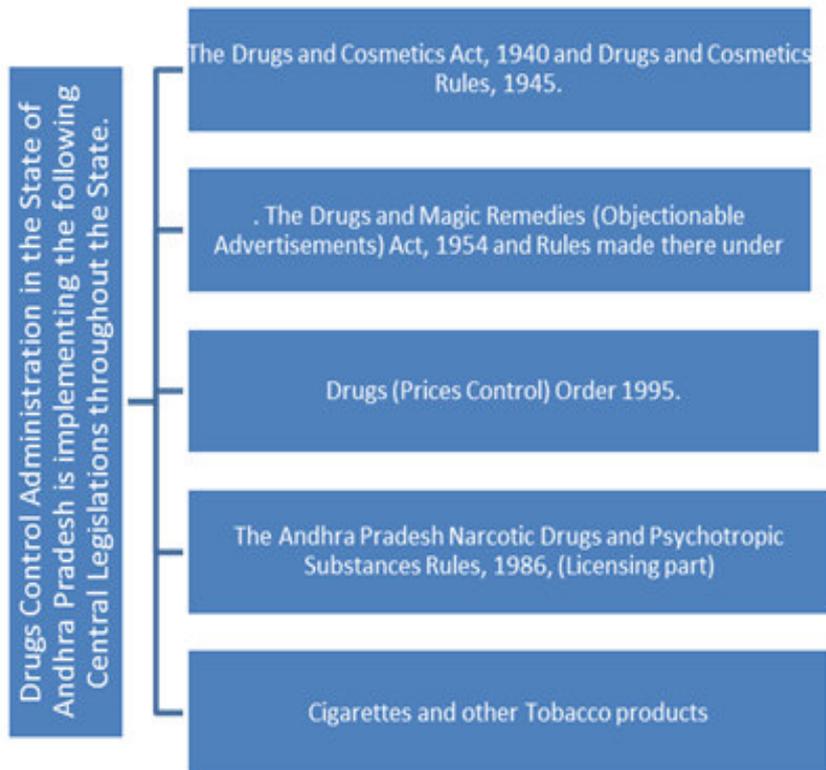


Figure 2
Impementation of Legislations

The organizational set up of various functionaries in Drugs and Control Administration are broadly classified into two wings.

1. Enforcement Wing.
2. Laboratory Wing.

ORGANISATION CHART

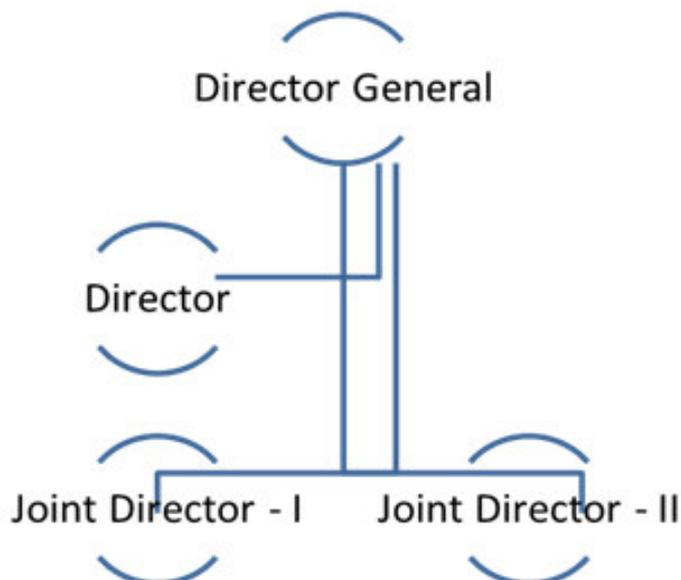


Figure 3
Organogram showing organizational set up

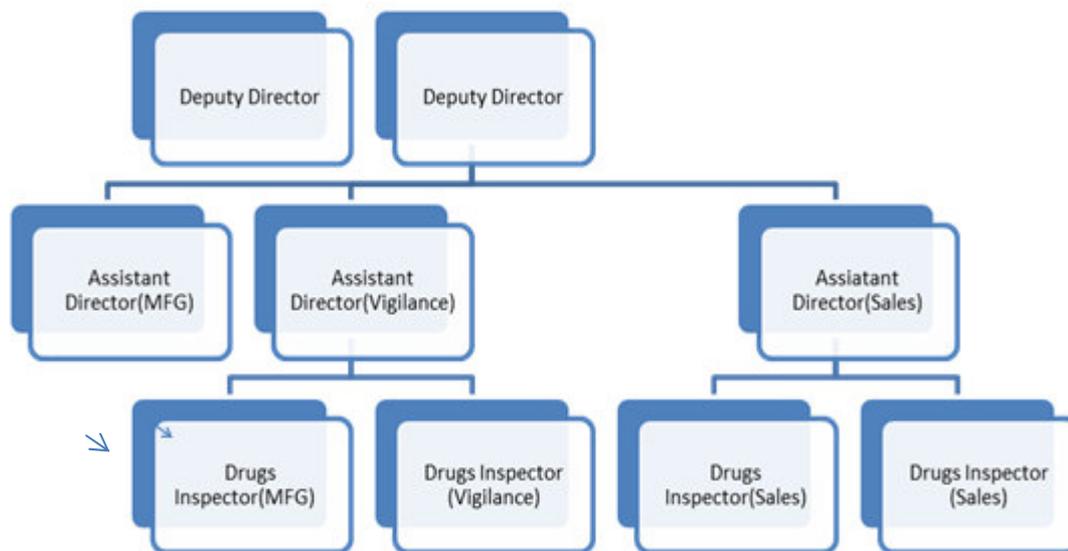


Figure 4
Organogram showing the organizational set up at Enforcement Level

ORGANIZATIONAL STRUCTURE FUNCTIONS DUTIES

- Director, Licensing Authority & Controlling Authority – 1 post Oversees the following activities / Enforcement functions by subordinate officers of the Drugs Control Administration in a view to achieve the supply of quality drugs at affordable prices to the public.
- Periodic and surprise inspections of manufacturing units (engaged in manufacture of drugs / cosmetics), sales outlets, medical stores attached to government institutions/hospitals.
- Laboratory analysis – collecting samples of drugs of cosmetics for tests or analysis, scrutinizing the claims of medicines, → Grant / Renewal of manufacturing Licenses. → Grant / Renewal of NDPS Licences → Coordinating with other State Drug Control Authorities and Drugs Control General of India.
- Joint Director – 3 posts (Enforcement) Licensing Authority & Controlling Authority
- JD-I: JD-II:
- The Joint Directors in the jurisdiction allotted are also the Licensing Authorities for manufacturing units of Drugs and Cosmetics and they oversee the above activities/enforcement functions of the subordinate officers concerned to their jurisdiction.
- Helps the Director in grant/renewal of manufacturing licenses, Narcotic and Psychotropic substances licenses, cancellations/suspension of manufacturing licenses.
- Joint Director (E) guides his subordinates → Grant / Renewal of manufacturing Licenses. → Coordinating other Regional Deputy Directors. → Issuance of various non-statutory certificates for the purpose of 3 Deputy Directors general (8 Posts)
- There are Deputy Directors posted in the state at Vishakapatnam, Eluru, Guntur, Kurnool, Warangal & Hyderabad Region. There are two Deputy Directors at Headquarters.
- The Deputy Director helps the concerned Licensing Authorities for grant/renewal of manufacturing licenses, Narcotic and Psychotropic substances licenses, cancellations/suspension of manufacturing licenses
- Issue of various certificates. → Oversees the achievement of inspection and sample targets by the subordinates officers (Drugs Inspector). → Conduct of Joint inspections and raids.
- Guides the subordinates in day to day work and on legal cases also.
- Supervise the work of Assistant Director / Drugs Inspector of area concerned. → Court Cases.
- Assistant Directors (13 posts) • There are twenty nine posts of Assistant Directors (AD) posted in the state at Srikakulam, Vizianagaram, Vishakapatnam, Rajahmundry, Eluru, Vijayawada, Guntur, Ongole, Nellore, Tirupati, Anantapur, Kadapa, Kurnool, → Oversees the achievement of inspection and sample targets. → Conduct of 5 D raids.
- Drugs Inspector • DI's are allotted different areas in the state A.P for administrative functioning, though the Statute empowers them for the entire state of Andhra Pradesh.
- The DI is the field enforcement officer for detection and investigation of offences → Achievement of inspection and sample targets → Conduct of raids → Follow-up of court cases. Figure.3 and 4)
- Joint Director (Laboratory) – He/ She is the highest officer in the Laboratory wing and supervises the functioning of the two Drug Testing Laboratories in the State, one at Vijayawada and one at Hyderabad. → Achievement of sample testing targets → Introduction of new protocols, procedures
- Senior Scientific Officer – He/ She is the second in line in the laboratory wing and is also the notified Govt. Analyst for Drugs Control Laboratory at

- Hyderabad and Vijayawada and the final authority on test results. • Supervises the work of Junior Scientific
- Achievement of sample testing targets → Quality assurance
 - Junior Analyst – He/ She receives samples and conducts tests/analysis as per the standards and requirements and submits them to the Junior Scientific Officer. He is responsible for maintenance & calibration of the lab equipment. → Achievement of sample testing targets

- Assistant Director (Non-Technical) – Establishment related matters • Budgetary and cost control • Infrastructure development and up gradation based on departmental priorities • Organizational Discipline • Maintain statistics related to all programs • Receiving and examining tappals, taking dictation, maintaining records, telephone operator → He supervises Administrative staff under his control. ^{2,3} (Figure 5)

ORGANISATION AT LABORATORY LEVEL ONE DRUGS TESTING LAB AT (GUNTUR)

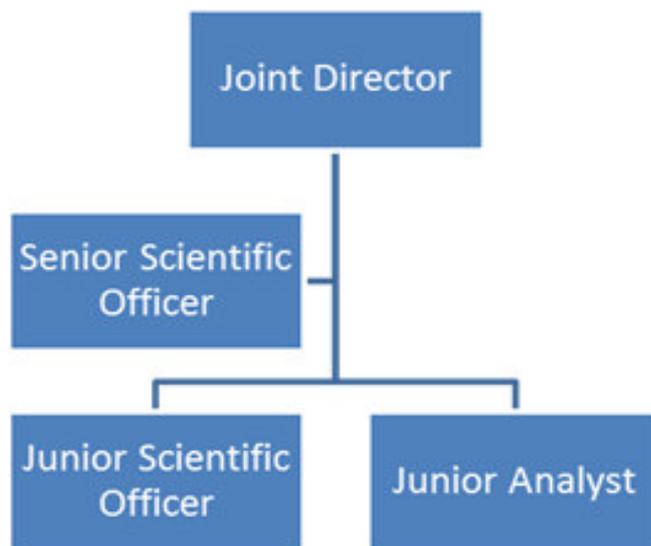


Figure 5
Organogram for Testing Laboratory

ACTION ON NOT OF STANDARD QUALITY

Spurious, Adulterated and Seized Drugs. The complete investigated file will be placed before Review committee for thorough examination and remarks. The remarks offered by the Review committee will be perused and may or may not be approved by the Director General. The Director will take the final action viz. Legal or Departmental based on the approved remarks by review committee and issue instructions and proceedings accordingly.

ACTION ON VIOLATIONS

reported by Drugs Inspectors / Assistant Directors: On receipt of the Inspection report of any licensee under the Drugs and Cosmetics Rules 1945, if it reports any

violations the concerned Licensing authority (Director / Joint Director in case of Manufacturing Licensee and Regional Assistant Director in case of Sales licensees in their region) will issue show cause notice to the licensee. If any reply is received from the licensee, the same will be referred to the concerned officer to offer their remarks. The Licensing authority will examine the reply submitted by the licensee and remarks offered by the concerned officer and action like suspension or stop production order or cancellation of drug licensees will be taken. They will be implemented by the concerned Inspecting Officer. There are about 197 Manufacturing Unit in Andhra Pradesh. There are about 121 Blood Banks and 60 Blood storage Centre in Andhra Pradesh. There are more than 25000 retailers and 5000 wholesalers. (Figure 6)

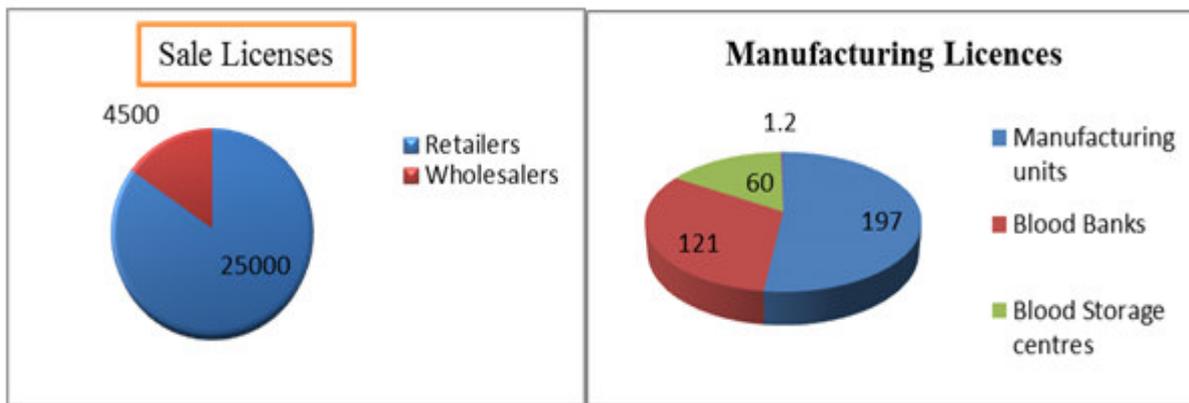


Figure 6
Total number of Sales and Manufacturing Licences in Andhrapradesh

SERVICES PROVIDED BY THE DEPARTMENT

- 1) Grant of manufacturing Licenses 60 working days
- 2) Renewal of manufacturing licenses 60 working days.
- 3) Grant / Renewal of approval for Approved Laboratories 45 working days
- 4) Approval of Additional Products 21 working days
- 5) Approval of Technical Staff 21 working days
- 6) Recommending for Grant/Renewal of Licenses to Central Licensing Authority, Delhi with respect to 60 working days
- 7) Effecting changes in existing licenses 21 working days
- 8) Issue of Free Sale certificate 7 working days
- 9) Issue of Market Standing certificate 7 working days
- 10) Issue of GMP certificate 15 working days
- 11) Issue of Non-conviction certificate 7 working days
- 12) Issue of Production capacity certificate 7 working days
- 13) Issue of WHO GMP certificate 60 working days
- 14) Grant of Sale Licenses 30 working days
- 15) Renewal of Sale Licenses 60 working days
- 16) Effecting change in existing sale licenses 30 working days.^{2,3}

PHARMACEUTICAL INDUSTRY

Andhra Pradesh's pharmaceutical cluster has grown from a single company owned by the central

government into one of the world's largest producers of bulk drugs. There are many other pharmaceutical clusters throughout India, and their emergence is largely due to the changing policy environment in the country. India being a predominantly poor country has a large need for life saving drugs but lacks the means to pay market prices for them. In 1970, the Indian government passed the Patents Act which allowed manufacturing processes in pharmaceutical products to be patented, but not the underlying products. This law allowed Indian pharmaceutical companies to reverse-engineer existing drugs and provide them to Indian consumers at a lower overall cost (as these companies did not have to recoup the large R&D investment made by foreign competitors. This led to a rapid expansion in the number and profitability of domestic pharmaceutical companies in India. The companies focused on manufacturing and were able to exploit the low cost of labour in India. In Andhra Pradesh (AP), the sector evolved in a comparable fashion but was also aided by high quality human capital, above average infrastructure, and helpful government incentives. Institutes for collaboration (IFC) also assisted in the development of the cluster.

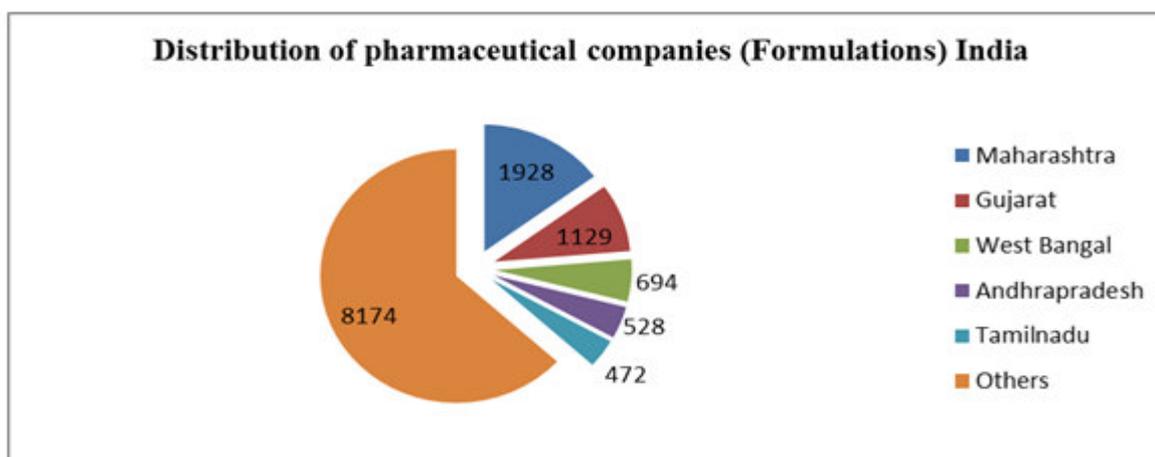


Figure 7
State wise Pharmaceutical companies (Formulations) in India

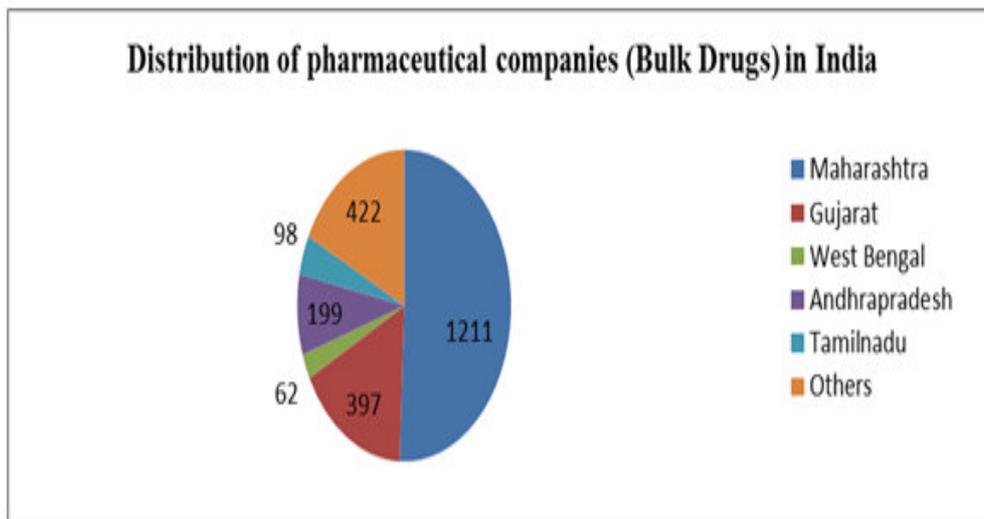


Figure 8
State wise Pharmaceutical companies
(Bulk Drugs) in India

There are several pharmaceutical clusters in India. AP's pharmaceutical cluster is competing primarily with related clusters in Maharashtra and Gujarat. While AP ranks third in overall pharmaceutical production, the state is the leading provider of bulk drugs for generic pharmaceuticals while Maharashtra and Gujarat focus on formulations. In terms of Special Economic Zones (SEZs), AP has more than 15 approved SEZs 62 for pharmaceuticals and bio-technology, more than in any other state.⁴(Figure 7 and 8)

EDUCATION

AP (and especially Hyderabad) has historically been one of India's primary destinations for investment in industry and human capital. It has numerous educational institutions. Every year AP generates 35,000 skilled graduates, including 81,000 engineers and 10,000 management professionals—approximately, 23% of all of India's software professionals come from AP20. Additionally, there a large number of institutes dedicated to the life sciences, including the Indian institute of Chemical Technology and the Centre for Cellular and Molecular Biology AP has become a hub for various activities relating to the pharmaceutical industry. The broad Segmentation of companies consists of manufacturers of APIs, manufacturers of formulations (finished dosage forms), CROs (Contract Research Organizations), CMOs (Contract Manufacturing Companies), and those companies involved in bio sciences, bio-equivalency studies, and clinical trials. The pharmaceutical industry in AP was initiated by large scale players such as IDPL (1967), Dr.Reddy's Laboratory (1984), and Aurobindo Pharma (1986). Some of the other key players in AP include Matrix (Mylan) Labs, Hetero Drugs, Divi's Labs, NatcoPharma, Neuland Labs, Gland Pharma, Granules India, MSN Labs, and Sri Krishna Pharma.⁴

ANDHRA PRADESH STATE PHARMACY COUNCIL

The Government of Andhra made 'Andhra State Pharmacy Council Rules, 1955 by G.O.Ms.1021,

Director of Medical health Services, Sultanbazar, Hyderabad, Dated 9th July 1955 in accordance with powers u/s 46 of The Pharmacy Act, 1948. Subsequently It came into existence by .O.Ms. 2073. Health, dated 15th July 1963 as Andhra Pradesh Pharmacy Council Rules, 1955. The Government of Andhra vide G.O. Ms. No.891, Health dated 8th December 1955 vide powers u/s 33A (4) of The Pharmacy Act, 1948 directed the Registrar Madras Pharmacy Council to prepare First register. It was published in the year 1956 with a list of 236 Pharmacists who were practicing pharmacy in the state of Andhra. Presently the registration of pharmacists is around 86000.Andhra Pradesh Pharmacy Council was formed on 19th March 1959. Due to many constraints elections for every 5 years to Pharmacy council were not conducted regularly. Though elections were held in 2003 and 2010 for the location of 6 members from registered pharmacists, this council has no legally and validity elected Council body or President. Now that the Council is functioning under In-charge, Director General, Drugs & Copyrights, Drugs Control Administration, Government of Andhra Pradesh with a Regular Registrar, 3 Regular Jr. Assistants and 8 out sourcing staff. Presently Director General, Drugs Control of AP is in-charge of the Council. . The main objective of the Andhra Pharmacy Council is to regulate the profession and Practice of Pharmacy in the State of Andhra Pradesh. The prime function of the APPC is to grant registration to the eligible pharmacists possessing requisite qualification as per the provisions of section 32(2) OF THE Pharmacy Act and to enforce the necessary provisions of the Pharmacy Act 1948 and Andhra Pradesh Pharmacy Council Rules, 1955. There are about 64 colleges in Andhra Pradesh.^{5,6}

CONCLUSION

The Drugs Control Administration and Manufacturing activity in Andhra Pradesh has witnessed tremendous expansion in last one decade. Andhra Pradesh has two hundred thirty six in 1956 to eighty six thousand

pharmacists in the state. The entire spectrum of the pharmacy related activities in Andhra Pradesh are brought under one roof, i.e., drugs control administration, pharmacy education, pharmaceutical Industry and trade business establishment for all around the development of pharmacy. The main objective to study the Regulation of Drugs in the state of Andhra Pradesh. Then comparing regulation of Drugs in other states and finally with the regulated countries like United states of America and Europe. By this we can find the difference in regulatory requirements among the

states of India. To strengthen the Regulatory system in India

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CONFLICT OF INTEREST

Conflict of interest declared none.

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