



Pharmaceutical Cluster in Andhra Pradesh

Microeconomics of Competitiveness

Final Project

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1 Executive Summary

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 labor in India. In 2005, in order for India to gain admission into the WTO it was forced to meet the Trade Related Aspects of Intellectual Property Rights (TRIPS) requirements. TRIPS required that countries honor and enforce the 20-year international product patents. This provided the IP protection that multinational firms demanded and encouraged investment in the Indian pharmaceutical industry.

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. However, coordination among firms as well as with related and supported industries remains low, which has led to a weak cluster. This paper's primary recommendations for strengthening the cluster include:

- (1) Enhance Drug Discovery: eliminate price controls on new products and provide incentives
- (2) Improve Doing Business Index Ranking: computerize procedures for property registration and

simplify the VAT system

- (3) Enhance information sharing amongst pharmaceutical companies: consolidate IFCs and establish forums for sharing information
- (4) Encourage companies to invest in specific areas that serve local demand: tax breaks for target areas and government funding for basic research
- (5) Build cluster reputation and strengthen export promotion bureaus to attract FDI: strengthen role of export promotion bureau and provide strict enforcement of quality standards
- (6) Enhance supporting and related industries: encourage coordination between industries by co-locating related companies and strengthen supplier base by encouraging FDI in the chemicals industry

2 Introduction to India

India is the largest democracy in the world with an estimated population of more than 1.2 billion people¹, making it the second most populated country in the world. The population is ethnically extremely diverse as people are divided based on religion, region, language, caste and race. The capital city is New Delhi, while Mumbai is the commercial and financial capital of the country. The country spans 3.3 million square kilometers², or roughly one-third the size of the U.S. and is 7th in the world. India has a



coastline of 7,000km on the Indian Ocean and the Bay of Bengal³. With regards to topography, India has three major geographic regions⁴: (i) Himalayan mountains, protecting the northern part of the country,

(ii) the flat Indo-Gangetic Plain, and (iii) the Peninsula (including southern tableland of the Deccan Plateau). Each of these regions has a series of river systems running through them. The climate is generally hot, with temperatures rarely falling below the freezing point below the Himalayan region⁵. The Indian federation comprises 28 states and 7 union territories.

2.1 History and Political Climate

India is one of the oldest civilizations in the world, with the birth of the Indus Valley civilization tracing as far back as 2500 BC⁶. The inhabitants at the time, thought to be Dravidians, subsequently migrated to the southern part of India, as the Aryan tribes of the Northwest provinces conquered and migrated to parts of North India and mixed with the indigenous tribes. The mixture of these two civilizations over a course of 1,000 years created a majority of the present-day Indian culture and population. The words *India*, *Hindu*, and *Hindi* come from the ancient Sanskrit word, *Sindu*, which was used by the Aryan people for the Indus River. India was ruled by a number of dynasties since the Maurya Empire in 4th century BC, each of which brought in new forms of science, art and culture to Indian society. Hinduism and its two offshoot religions (Jainism and Buddhism) are followed by the majority of India, while Islam was introduced in the early-700s by Arab traders, and further spread with invasions from present-day Afghanistan and the formation of the Mughal Empire in the 16th – 19th centuries. While all previous invasions came from land from Northwest India, the British were the first to conquer from the sea. Europeans started arriving in India around the 16th century, and by the 19th century, with the fall of the Mughal Empire, the British were the dominant political power on the subcontinent⁷. After years of struggle, India gained independence from the British in 1947, led by Mahatma Gandhi and Jawaharlal Nehru (part of Indian National Congress party). As part of the independence process, the Muslim-majority states were carved out to form a separate country under the leadership of Muhammad Ali Jinnah, to form what is today Pakistan and Bangladesh. The Indian

National Congress has been the dominant party in Indian politics since independence (ruling party for 53 of the last 66 years).

The Indian Constitution provides for a parliamentary, republican and federal system and was promulgated in 1950⁸. The President of India is the Head of State, and the Prime Minister is the Head of the Government, and exercises a majority of the executive power. There are two houses in the Legislative branch: Rajya Sabha (upper house) and Lok Sabha (lower house). State governors, as appointed by the President had large amounts of political power in their territories. The judicial system is based on British common-law practices.

2.2 Competitive Positioning of India

2.2.1 Endowments

The table below illustrates some of the strengths and weaknesses in India's key endowments:

<i>Large and Young Population</i>		India's population of 1.2B is the 2 nd largest in the world with a median age of 28 years (vs. China and Japan levels of 38 years and 44 years, respectively). Developed countries are witnessing rising average age levels as the elderly live longer and fertility rates are falling.
<i>Fertile Land with Plenty of Fresh Water</i>		India has access to the Himalayan river network that provides a perennial supply of fresh water and fertile land masses to feed its large and growing population. In addition, the river network allows goods to be transported from the center of the country out to the coasts to be shipped for exports.
<i>Strategic Location on Indian Ocean</i>		India has 7,000 kilometers of coastline located on the Indian Ocean along a vital shipping lane ⁹ .
<i>Lack of Natural Resources</i>		India is a significant net importer of energy. India depends to a large extent on domestic coal reserves and hydroelectric power to provide electricity to its growing population. Efforts are being made to increase extraction of coal for power generation. 50% - 60% of total exports spent on importing oil resources. Domestic demand for oil expected to increase from 2.9mm bbl/day in 2006/2007 to 7.1mm bbl/day in 2030 and domestic

Regional and Internal Conflict



natural gas demand expected to increase from 38bcm in 2006/2007 to 117bcm in 2030¹⁰.

India borders Pakistan, Bhutan, China, Bangladesh and Nepal. Regional trade and co-operation is limited and India spends significant resources on its border dispute with Pakistan. In addition, the levels of poverty vary dramatically within India's borders from one state to another. This non-inclusive growth has fueled internal conflicts in India (e.g. Maoist movement in central and east India)

2.2.2 Economic Performance To-Date and Macroeconomic Policy

Pre-Liberalization of Economy (1947 – 1991)

Since its independence in 1947, to the late 1980s, India pursued an economic development strategy closely resembling the Soviet model – i.e. trying to modernize the Indian economy via strict government control. For example, the Government of India developed its first of many Five Year Plans in 1951. In addition, India created a large bureaucracy (largely a left over from the period of British rule) in order to execute on the planned economy strategy set by the Government. In fact, India had been named the “Permit Raj” due to its large (and relatively inefficient) bureaucracy. This Permit Raj was responsible for controlling economic resources, directing investment, and excluded private partners from investing in most sectors of the economy. In addition, the large number of permits required to operate a business under the Permit Raj prevented Indian companies from competing effectively due to delays, controlled production levels, barriers to entry, etc. High import tariffs and permit requirements encouraged domestic players to purchase goods from local, lower-quality, suppliers rather than importing from other countries. All these factors served to decrease the competitiveness of Indian businesses relative to other countries.

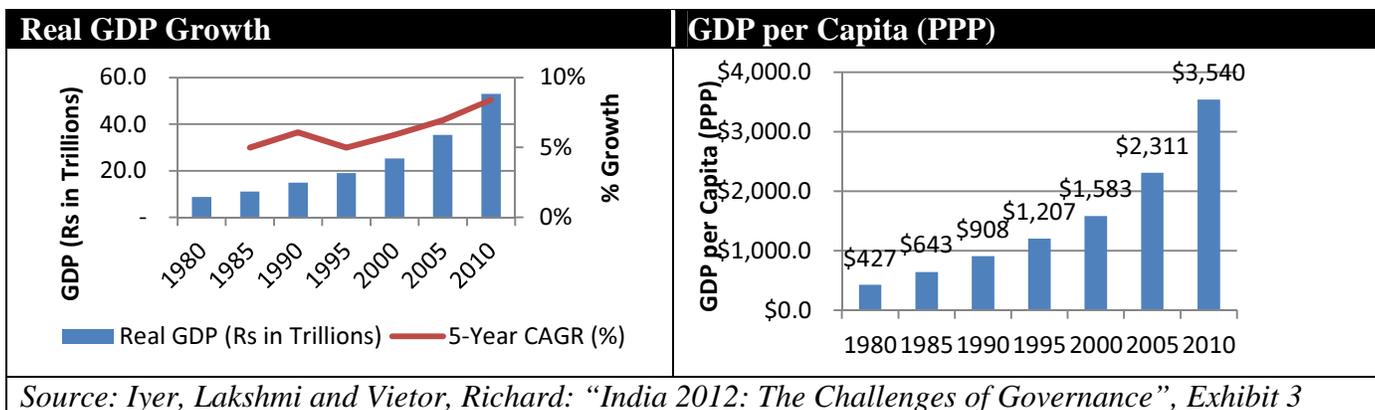
In addition, the period of foreign British rule, made the Indians adverse to foreign investment and involvement in domestic companies, limiting FDI and knowledge transfer. As a result of its close political and military relationship with the Soviet Union, Eastern Europe was a major trading partner for

Indian goods and services, representing 19.3% of exports in 1989¹¹. In addition to the poor competitiveness of Indian businesses, the Indian government's active involvement in the economy also resulted in large fiscal imbalances, causing the public debt level to rise rapidly. In June 1991, the Indian government experienced a significant balance of payments crisis driven by the large negative current account balance, rising oil price due to the Persian Gulf War and decline of the Soviet Union. As a result, India was forced to access funding from the World Bank and International Monetary Fund (IMF). As part of the loan package, the Indian economy was forced to comply with the IMF requirements of economic liberalization, "as described by John Williamson who coined the term 'Washington Consensus,' include: (1) deregulation, (2) privatization, (3) property rights, (4) fiscal discipline, (5) competitive exchange rates, (6) tax reform, (7) interest rate liberalization, (8) trade liberalization, (9) public spending on education and health, and (10) foreign direct investment liberalization."¹²

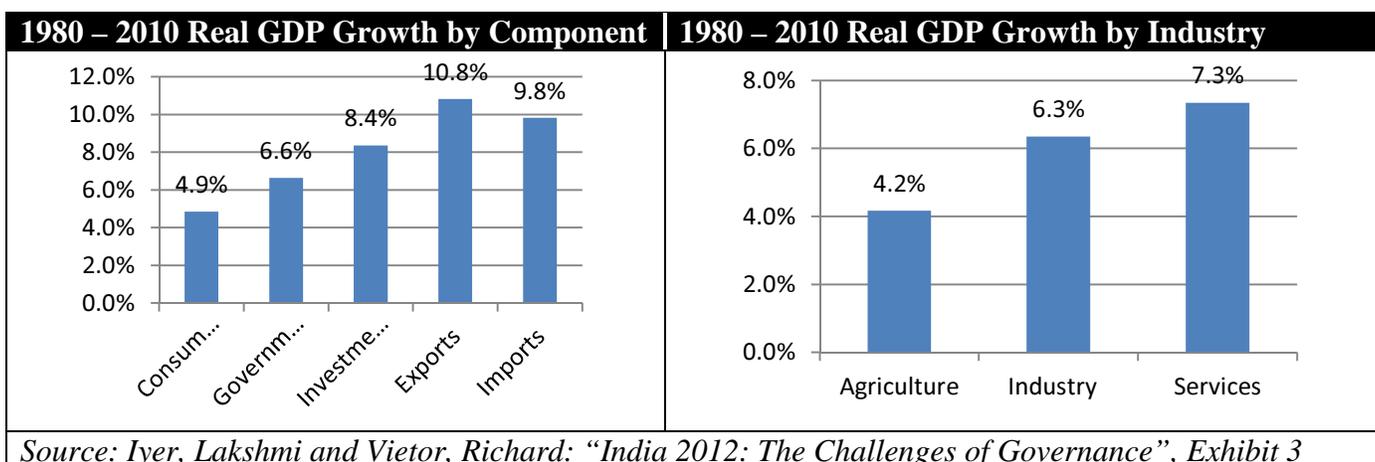
Transition to a Liberalized Economy

In the midst of the balance of payments crisis in 1991, the Congress Party returned to power under the leadership of Narasimha Rao, who assigned the role of finance minister to Dr. Manmohan Singh (current PM) in an effort to open up the economy to foreign trade and competition. As such, Dr. Singh introduced a number of changes to the economy, including: allowing FDI in select industries, reducing tariffs and taxes, reducing license and permit requirements and adopted a disciplined fiscal plan¹³. As a result of these initiatives, India experienced rapid economic growth and the private sector started moving up the value chain to export goods and services across the globe¹⁴.

The charts below illustrate the growth in the Indian economy post-liberalization:



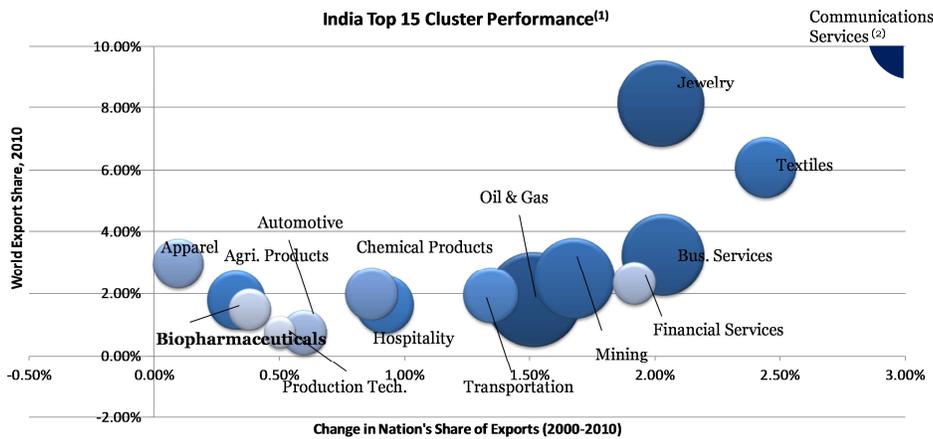
While consumption expenditures has continued to grow at a pace of 5% from 1980 to 2010, exports and investment expenditures have been the key growth drivers for the Indian economy, partially offset by higher growth levels in imports. Separately, India’s growth story has been driven primarily by expansion of the services sector. Indian companies are leading providers of IT services, business process out-sourcing (BPO), etc. The agriculture industry, by far the largest employer in the country has grown at only 4.2% over the last 30 years.



2.2.3 Summary of Export Clusters

The chart below¹⁵ illustrates the top 15 clusters in the Indian economy. Communication Services forms the largest cluster by a large margin

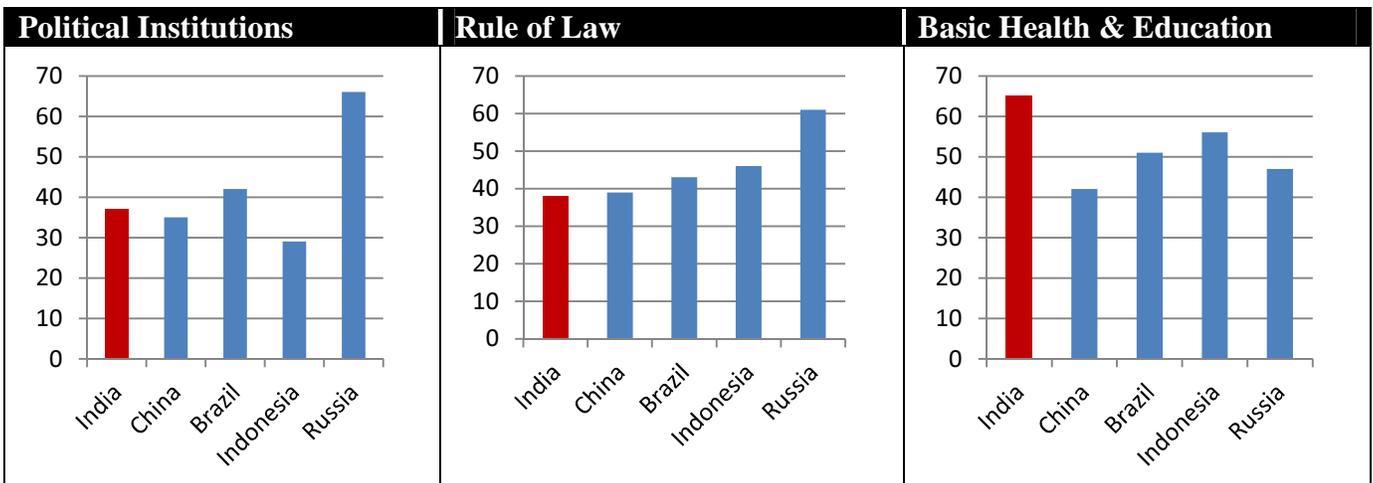
India Top 15 Cluster Performance



- (1) International Cluster Competitiveness Project, Institute for Strategy and Competitiveness, Harvard Business School
 (2) Communications Services cluster has a 18.43% share and has seen a 11.61% share change

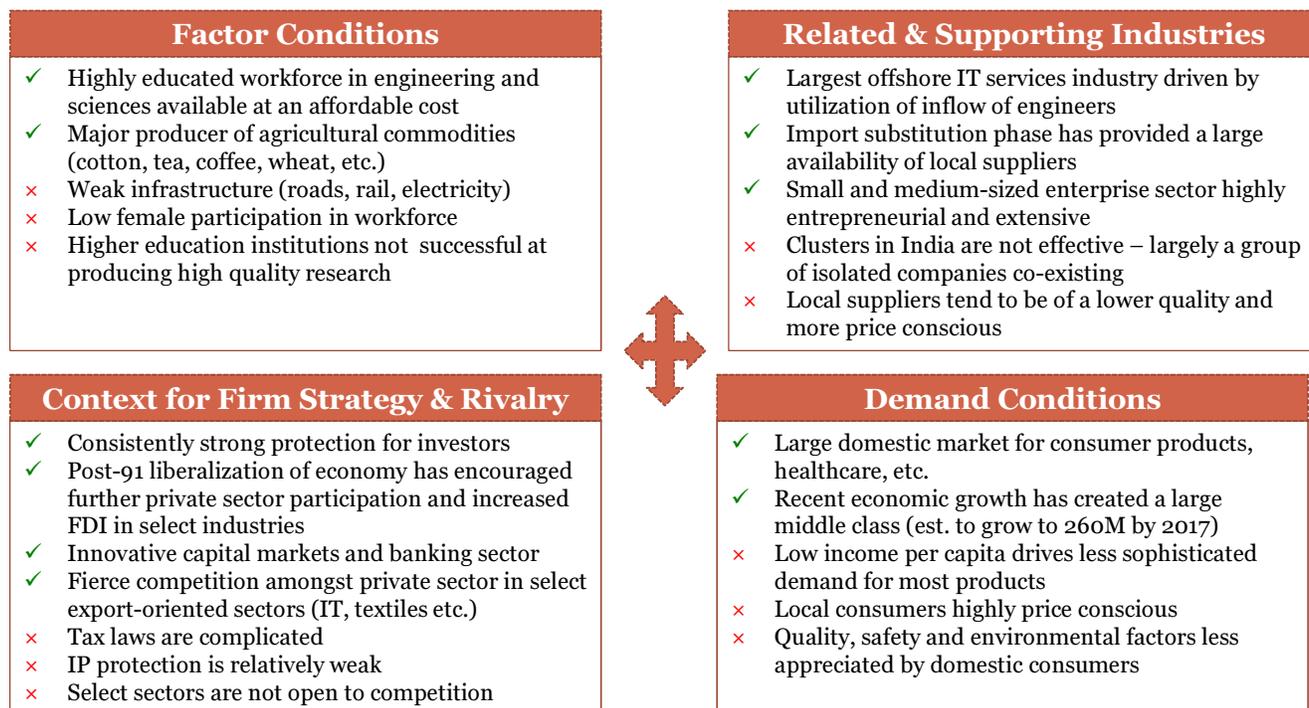
2.2.4 Social Infrastructure and Political Institutions

India's rule of law and political institutions are weaker than its peer group of rising emerging markets (Brazil, China, Russia and Indonesia). The Indian Government has failed to address weaknesses in its judiciary, creating a weak rule of law, as well as setting up adequate separation of powers in its political institutions. The parliamentary form of government adopted by India post-independence can create gridlocks in a system as vast and diverse as India; where minority groups create hold-outs, thereby not allowing the necessary legislation from getting passed. Regional parties have continued to gain popularity in India, further weakening the power at the center, and creating a greater hurdle for passage of necessary economic reform.



A staggering 33% of India continues to live on less than US\$1.25 per day – this figure is significantly higher than the peer group (China is at 13%), and working to increase people out of poverty will and should continue to be a major priority for the government.

2.2.5 India Diamond



3 Andhra Pradesh

Andhra Pradesh (AP) is India’s fourth largest state by area (275,045 km²) and fifth largest by population (84,655,533 as of 2011). Hyderabad is AP’s capital 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).



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

the majority of AP residents (95%) with small minorities practicing Islam, Christianity, Buddhism, Jainism, and Sikhism. The state has a varying climate with hot summers (especially on the coastal plain) and monsoons from July to September.

AP's Gross State Domestic Product (GSDP) in 2011 was Rs 567,636 crore (US\$113.5 bn) which had a CAGR of 8.9% over the past 7 years (compared to 8.4% for the rest of India). Its per capita income grew at 12.7% per year over the same time period (compared to 10.9% for the rest of India)¹⁶.

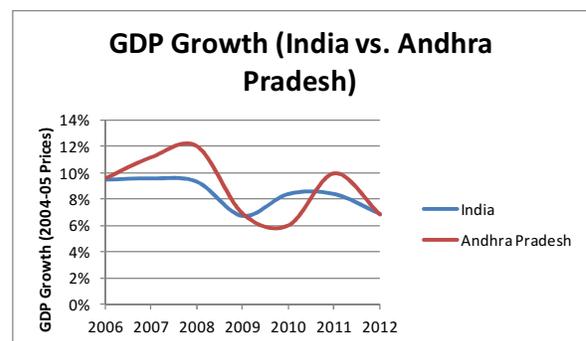
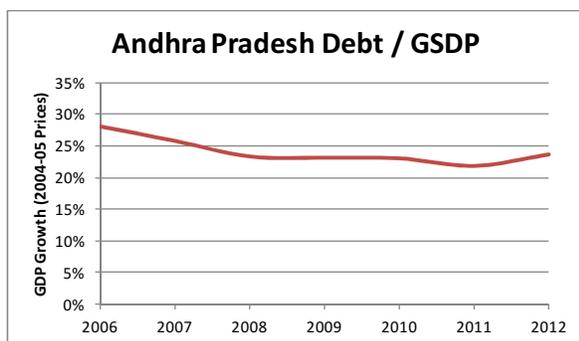
3.1 Competitive Positioning

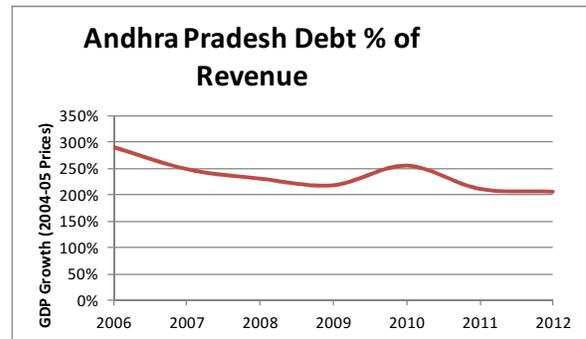
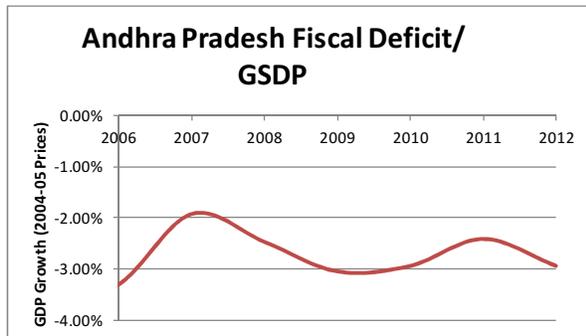
3.1.1 Endowments

AP benefits from having abundant fertile land and water resources as well as favorable climatic conditions¹⁷. Its leading crops include tobacco, dry chilly, groundnut, and sugar. Its long coastline has also led to a vibrant marine industry. It is also a major source of mineral resources and has the second largest reserves among Indian states. Its large limestone reserves have led to strong cement and engineering industries.

3.1.2 Macroeconomic Policies

As the below charts show¹⁸, the AP government has been successful in stabilizing the state's fiscal deficit and to lower its debt.





AP's debt/GSDP ratio has decreased from 28% to 24% over the past 6 years while its debt/revenue ratio has gone from close to 300% to 200% over the same period. This has been part of a wider goal to promote AP as a destination for investment. As the below tables show¹⁹, AP has seen inflation and poverty rates less than India.

Poverty Rates

	Andhra Pradesh			India		
	Rural	Urban	Total	Rural	Urban	Total
1983	27%	37%	30%	46%	42%	45%
1993-94	17%	38%	22%	37%	33%	36%
2004-05	11%	28%	16%	28%	26%	NA

Inflation

	Andhra Pradesh		India	
	General	Food	General	Food
1980	7.6%	8.0%	8.5%	8.5%
1990	6.8%	6.6%	7.3%	7.3%
2001	9.5%	9.8%	9.3%	9.3%
2006	3.4%	3.4%	3.5%	3.5%

Microeconomic Policy: Diamond Analysis

Factor Conditions

- ✓ Highly educated workforce in engineering, commerce, and science
- ✓ Large number of institutes focused on the life sciences
- ✓ Infrastructure better than the Indian average
- ✗ Poor primary education system
- ✗ Low female participation in workforce

Related & Supporting Industries

- ✓ Large IT cluster has led to major investments in infrastructure and education as well as institutes focused on the life sciences
- ✗ Few major industries directly related to pharmaceuticals
- ✗ Raw products are increasingly being sourced from China



Context for Firm Strategy & Rivalry

- ✓ Pro-business government has put in place major incentives including cost/investment reimbursements and subsidies for worker training programs
- ✓ Setup of IDPL in Hyderabad by the central government was a major precursor to the industry
- ✓ Infrastructure development funds have been setup by the government

Demand Conditions

- ✓ Large domestic market for healthcare
- ✓ Recent economic growth has created a large middle class
- ✗ Low income per capita drives less sophisticated demand for most products

3.1.3 Demand Conditions

AP has demand conditions very similar to the rest of India. The state's primarily poor population

is an obvious source of demand for generic pharmaceuticals which still make up the vast majority of the cluster's output.

3.1.4 Factor Conditions

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, including over 1,300 arts, science, and commerce colleges, over 1,000 MBA and MCA schools, 226 engineering colleges, 53 medical schools, and one Indian Institute of Technology (in Hyderabad). 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.

3.1.5 Context, Strategy, and Rivalry

The state has taken major measures to upgrade its physical infrastructure through the implementation of funds dedicated to infrastructure— the Industrial Infrastructure Development Fund (IIDF) and the Critical Infrastructure Balancing Fund (CIBF). It has also made private sector participation in infrastructure development a priority. To that end, it setup the Infrastructure Authority (IA) whose mission is to attract private sector financing and construction of infrastructure projects. AP has also benefited from special economic zones setup by the national government which attracts investment by offering lower tax rates and fewer administrative burdens.

3.1.6 Related and Supported Industries

AP's large information technology and pharmaceutical cluster have led to major investments being made in infrastructure and education. Many technology and engineering schools have supported the development of institutions focused on the life sciences. The large agriculture industry in AP is an

import source of inputs for the pharmaceutical cluster; however, raw materials are increasingly being sourced from neighboring China because of cost advantages.

4 Pharmaceutical Cluster

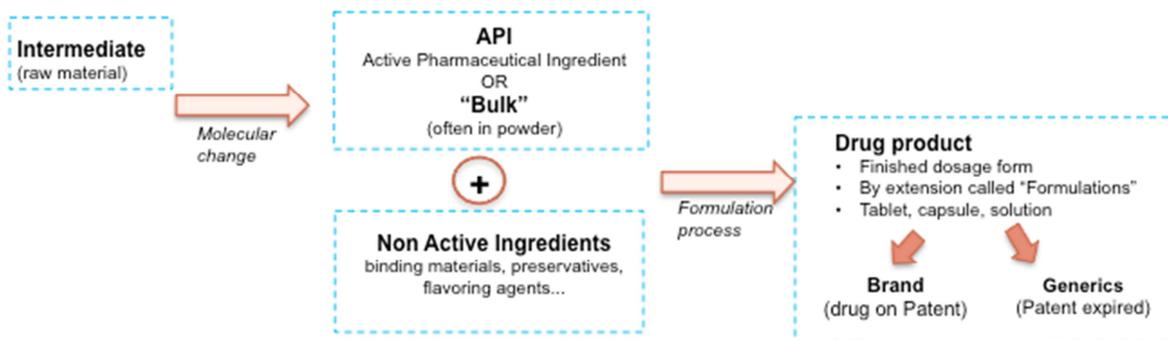
4.1 Value-Chain Overview

Value Chain²¹:



The pharmaceutical process begins with investing in R&D and attempting to develop new drugs, followed by the patenting phase (a patent has a 20-year time period including the clinical trials phase). Clinical trials have different phases (I, II, III), and they aim to ensure the security, efficacy, and finally the appropriate dosage of the drug. Upon completion of trials, drugs are submitted for approval by a regulatory body (e.g. FDA for drugs sold in the US, Central Drugs Standard Control Organization for drugs sold in India). Once the drug is approved it is manufactured and distributed through an extensive sales and distribution network often controlled by the pharmaceutical company.

Historically, Indian companies have focused on the manufacturing phase of the value chain, with limited investments in R&D. Within the manufacturing process, different materials must be sourced and brought together. Intermediates are materials that must undergo further molecular change in order to be converted to active pharmaceutical ingredients (API)²². APIs are mixed with non-active excipients (binding materials, preservatives, flavors, etc.) and, through the formulation stage, are converted to the final medicinal product²³. The final drug product can either be branded if the intellectual property is protected via a patent or considered generic if the patent on the product has expired (or is not recognized in the particular market).



4.2 Global Pharmaceutical Industry

The global pharmaceutical market in 2009 was estimated to be worth US\$837 billion by sales²⁴. Global dollar volume sales of pharmaceutical products are heavily concentrated in developed markets (the US alone accounts for 36% of sales²⁵ and the US/Europe/Japan collectively account for over 75% of sales²⁶). The top 10 global markets in 2009 were: the US, Japan, France, Germany, China, Italy, Spain, UK, Brazil, and Canada. The global generic pharmaceutical market was estimated to be worth US\$88 billion in 2009 and is forecasted to reach US\$130 billion by 2014²⁷. In 2009, pharmaceutical and biotechnology companies spent US\$65 billion on R&D, 70% of which was spent in the US. The table below provides a snapshot of key regions competing in the global pharmaceutical market:

Country /Region	Position (based on 2009 sales)	Specificities	Other elements
U.S. 	Largest market for pharmaceuticals (36% of sales)	<ul style="list-style-type: none"> 70% of global R&D expenses (from firms) spent in the US²⁸ Manufacturers spend US\$65B on R&D in 2009²⁹ 	<ul style="list-style-type: none"> Free-pricing market Favorable patent and regulatory environment Vibrant research and innovative sector Established capital markets and venture capital industry World class research institutions
European Union 	#2 region (32% of global sales)	<ul style="list-style-type: none"> Largest countries in terms of value: Germany, France, UK, Italy 	<ul style="list-style-type: none"> Limited R&D vs. US
China	Expected to grow	<ul style="list-style-type: none"> China and India collectively 	<ul style="list-style-type: none"> Demand for care rising

	to #3 country for prescription medicines (after US and Japan)	provide 40% ³⁰ of US API needs and provide intermediates to Indian companies <ul style="list-style-type: none"> • 19% of market represented by traditional Chinese medicine, 62% prescription, and 18% OTC³¹ • Multinationals' share of Chinese market was 25% in 2010³² 	sharply <ul style="list-style-type: none"> • Lack of coordination among regulatory bodies: obstacles to market access • Fragmented market - Strong local competition
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4.3 Indian Pharmaceutical Industry

4.3.1 Historical Context

India has a rich history of ayurvedic (or traditional) medicinal practices. The growth of allopathic medicine in India was a gradual process. The advent and expansion of the pharmaceutical industry in India can be divided into four key periods:

Prior to 1970: The Drugs and Cosmetics Act (1940) regulated the import, manufacture, distribution and sale of drugs in India. This was followed by the Pharmacy Act (1948) that heavily regulated pharmacies in India. During this period, several foreign companies entered the Indian market and were the major pharmaceutical suppliers to local pharmacies. There was limited domestic participation and competition. The prices of drugs in India were amongst the highest in the world³³.

1970-1990: The Patents Act (1970) was introduced allowing for manufacturing processes in pharmaceutical and agro-chemical-based products to be patented, but not the underlying products³⁴. The passage of this law allowed Indian pharmaceutical companies to reverse-engineer existing drugs and provide them to Indian consumers at a lower cost (as these companies did not have to recoup the investment in R&D). This led to a rapid expansion in the number and profitability of domestic pharmaceutical companies in India.

1991-2005: Major economic reforms were introduced in India in 1991, leading to an increase of foreign investments in the economy. Domestic pharmaceutical companies expanded aggressively. The

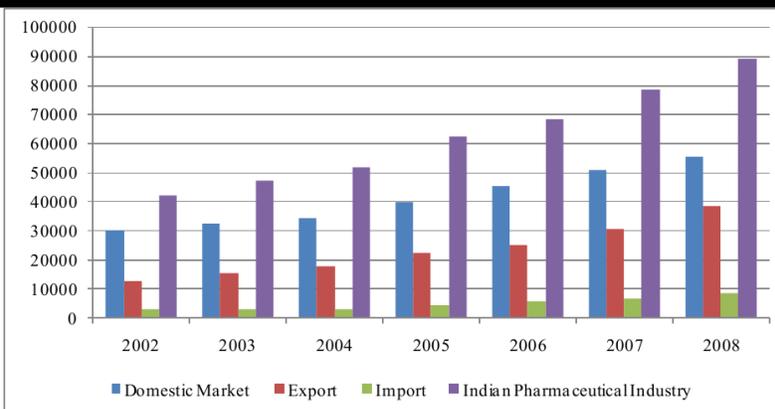
Drugs Price Control Order (DPCO) was introduced in 1995 to regulate the price of drugs. The pharmaceutical sector was open to 100% FDI via the automatic approval route in 2002.

2005 onwards: In 2005, India made substantial amendments to their patent laws as part of its efforts to comply with WTO’s Trade Related Aspects of Intellectual Property Rights (TRIPS) requirements³⁵. The TRIPS agreement mandates that member countries must honor and enforce 20-year international product patents. This provided the comfort of IP protection to multinational firms and encouraged investment in the Indian pharmaceutical industry. Also, Indian companies continued to expand their distribution networks and set up manufacturing facilities abroad. In 2008, the Department of Pharmaceuticals was created under the Ministry of Chemical and Fertilizers. There is now a trend towards higher R&D investments due to the protection of product patents.

4.3.2 Industry Size

The pharmaceutical industry in India had a market size of US\$15.6B in 2011³⁶. The industry size is projected to grow to US\$55 billion by 2020³⁷. The industry currently comprises of more than 20,000 companies employing 4 million people. However, the largest 300 companies account for 70% of products on the market. As the figure below shows, on average around 70% of the overall India’s pharmaceutical industry size is dependent on the domestic market³⁸.

Components of Indian Pharmaceutical Industry (All figures in INR crores)



Source: Department of Pharmaceuticals Annual Report 2009-10

The table below summarizes the different components of India's pharmaceutical industry:

<i>Active Pharmaceutical Ingredients (APIs)</i>	<ul style="list-style-type: none"> • US\$9B export market as of 2010 • India is expected to be the second largest producer of APIs globally soon³⁹
<i>Contract research & manufacturing services</i>	<ul style="list-style-type: none"> • US\$3B market in in 2009 with more than 1,000 players⁴⁰
<i>Formulations</i>	<ul style="list-style-type: none"> • Domestic market size is currently valued at about US\$10B; substantial growth expected over the next five years⁴¹
<i>Bio-Similars</i>	<ul style="list-style-type: none"> • Expected to grow to US\$600M by 2013 from US\$200M in 2008⁴²

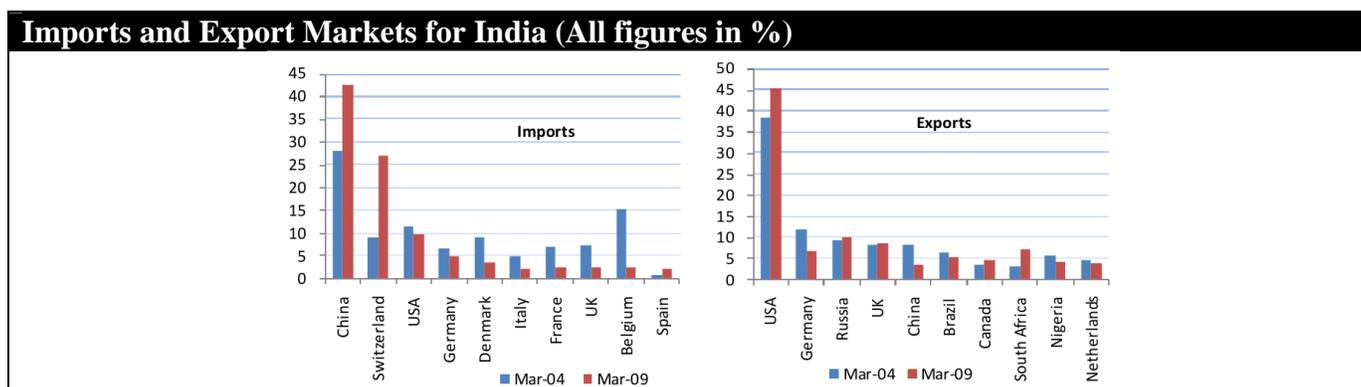
4.3.3 Competitive Advantage of Indian Pharmaceutical Industry

India is a significant source of pharmaceutical products for the domestic and export markets. The table below highlights India's key competitive advantages:

<i>Enhancing domestic market</i>	<ul style="list-style-type: none"> • Increasing economic prosperity • Increasing penetration of health insurance
<i>Diversified Portfolio</i>	<ul style="list-style-type: none"> • Over 60,000 generic brands across 60 therapeutic categories⁴³ • Manufactures more than 400 different APIs⁴⁴
<i>Cost Competence</i>	<ul style="list-style-type: none"> • Pharmaceutical production costs are almost 50% lower in India than in Western nations, while overall R&D costs are about one-eighth and clinical trial expenses about one-tenth that of Western levels.⁴⁵
<i>Skilled Workforce</i>	<ul style="list-style-type: none"> • Highly skilled and educated workforce

4.3.4 Import and Export markets

India exports pharmaceutical products to more than 65 countries. The U.S. is the largest market for Indian pharmaceutical products, comprising approximately 45% of exports, followed by Europe and select regions of Africa. With regards to imports, China and Switzerland represent the major sources for India⁴⁶.



Source: Department of Pharmaceuticals Annual Report 2009-10

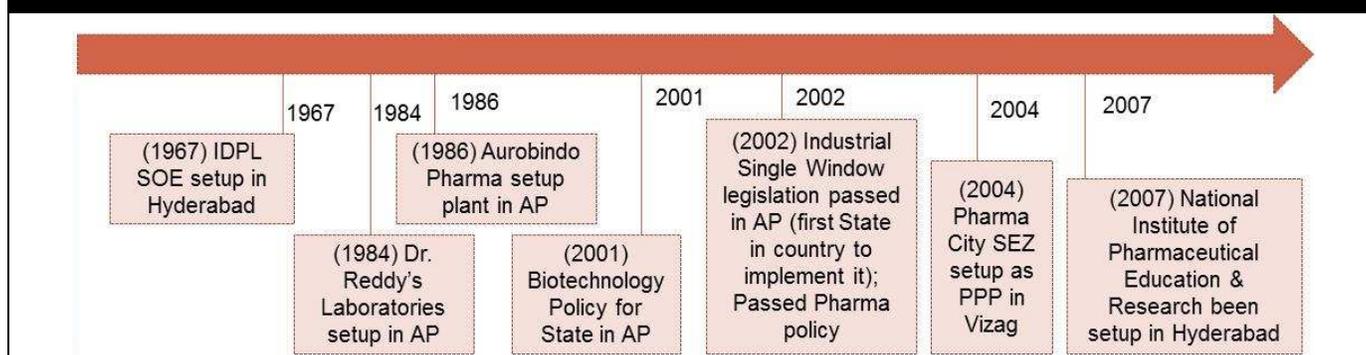
5 Andhra Pradesh Pharmaceutical Cluster

5.1 Why Andhra Pradesh?

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, Natco Pharma, Neuland Labs, Gland Pharma, Granules India, MSN Labs, and Sri Krishna Pharma.

Key milestones for pharmaceutical industry in AP



The development of the industry was well supported by the policy framework that encouraged better business environment development. AP was one of the first states to implement Industrial Single Window legislation in 2002⁴⁷. AP has also led the way in terms of setting the Biotech Policy way back in 2001 and also encouraging SEZs for Pharmaceutical and Biotech cluster.

In the past, the primary focus of AP's pharmaceutical companies has been on bulk drugs; indeed, it is responsible for one third of India's bulk drug production⁴⁸. These companies have expanded into formulations and CRAMS (Contract research and Manufacturing services). AP is also gradually getting

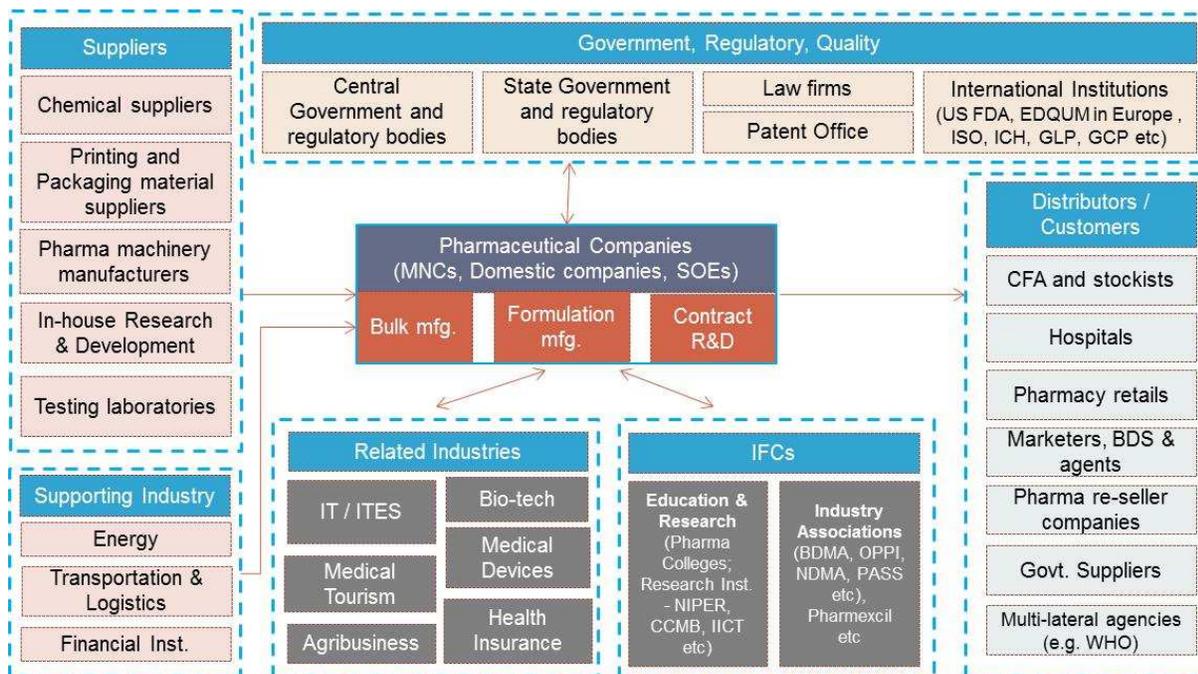
recognized for its biotechnology sector, with the prominent presence of companies such as Shantha Biotechnics (Part of Sanofi), Bharat Bio, and Biological Evans.

Healthcare institutions have also helped to strengthen the pharmaceutical industry. The major hospital chains are Apollo, Care, Global, Yashodha, Kamineni, Indo-American Cancer Institute, LV Prasad Eye Institute, and the Nizams Institute of Medical Sciences. These hospital chains are not only customers for pharmaceutical industry but also assist with clinical research for new medications.

Some of the key factors that helped AP become a hub for pharmaceutical industry are:

- a) Availability of skilled talent (due to the large number of universities and colleges)
- b) High connectivity of national and international destinations (due to connectivity by airports, roads and sea port)
- c) Large capacity plants approved by key regulatory authorities including the FDA (US), MHRA (United Kingdom), TGA (Australia), Health Canada, FDA (South Korea), Anvisa (Brazil), and Invima (Colombia).
- d) The support of the AP government through the creation of SEZs

5.2 Cluster Map



The AP cluster map exhibits a low degree of sophistication. Even though there are a large amount of actors, they tend to work in silos and have not been able to move up the value chain, instead relying on low manufacturing costs as a competitive advantage.

While a few pharmaceutical companies engage in R&D on contract, most have little R&D activities. These companies are able to generate adequate profits and return on capital by participating in the generic pharmaceutical market and are often unwilling to make the large upfront investments required to develop innovative new products that are globally competitive. In addition, there is also a lack of sophisticated suppliers, resulting in companies relying heavily on China for ingredients⁴⁹.

5.3 Select Pharmaceutical Companies in Andhra Pradesh

5.3.1 Dr Reddy's Laboratories Ltd

Dr Reddy's Laboratories Ltd (DRL) is headquartered in Hyderabad and has become India's second-largest pharmaceuticals company. It was one of the first large scale companies to set up in AP in 1984. In 1987, it obtained its first FDA approval for Ibuprofen API. In 1990, it became the first Indian

pharmaceutical company to export Norfloxacin and Ciprofloxacin to Europe and the Far East⁵⁰. Since then DRL has led the growth story of AP's pharmaceutical cluster. It manufactures APIs and finished dosage forms and markets them globally; it also conducts basic research in diabetes and cardiovascular diseases. The company is moving ahead with a purpose of providing affordable and innovative medicines through three core businesses—pharmaceutical services and active ingredients, global generics, and proprietary products.

DRL's revenues for 2012 were US\$2 billion with a CAGR of ~20% over the last decade⁵¹. It has expanded internationally by setting up API manufacturing plants in the UK and Mexico.

5.3.2 Aurobindo Pharma Ltd.

Aurobindo Pharma is among India's top five pharmaceutical companies in the country. It started in AP in 1986 and is a manufacturer of generic pharmaceuticals and APIs⁵². Based in Hyderabad, the company started with a specialty in generic formulations segment. Today it is transitioning into a knowledge driven company manufacturing APIs and formulation products. It is R&D focused and has a multi-product portfolio with manufacturing facilities in several countries. It aims to achieve US\$2 billion in revenues by 2015-16.

5.3.3 Indian Drugs and Pharmaceutical Limited

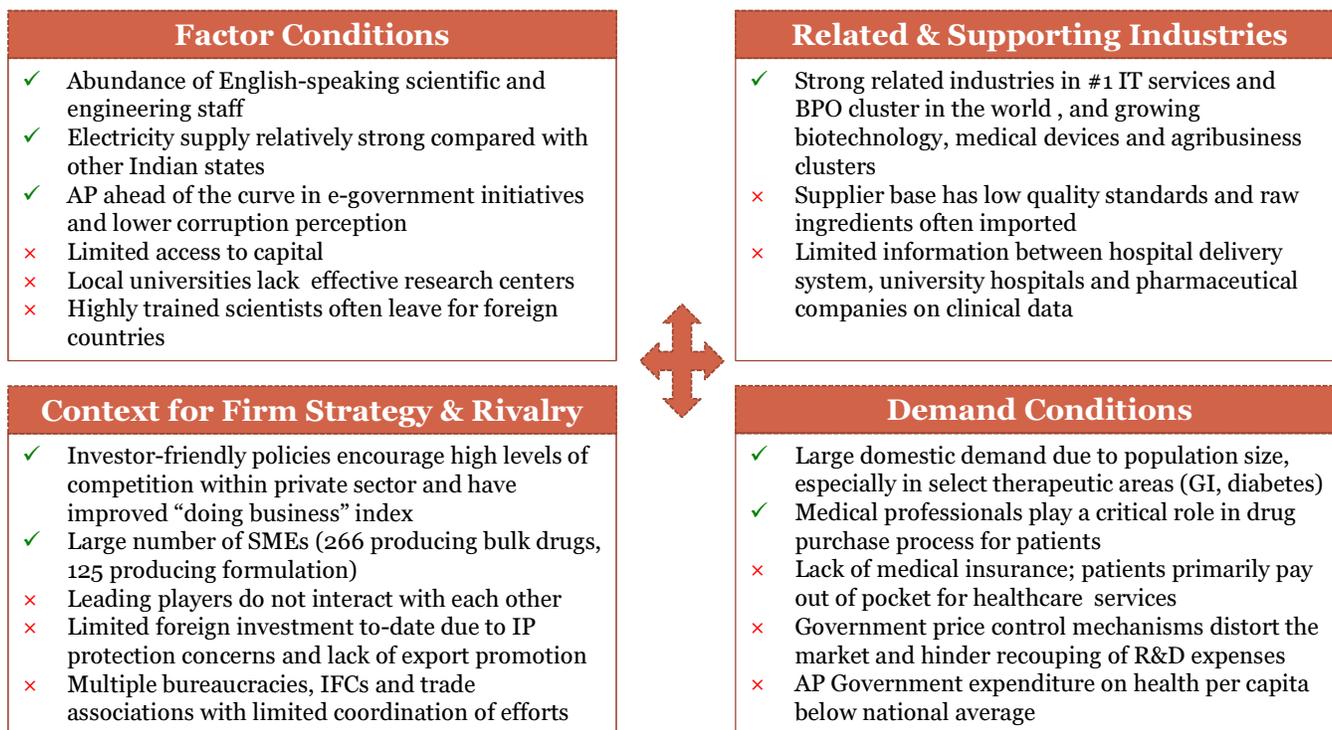
Indian Drugs and Pharmaceutical Limited (IDPL) is the largest government-owned pharmaceutical company in India. IDPL set up its Hyderabad manufacturing facility in 1967 and manufactures a wide range of bulk synthetic drugs⁵³. IDPL plays a key role in supplying drugs for large scale government health programs.

Name of Company	Gross Margin FY10 (%)
Aurobindo Pharma	24.1%
Dr. Reddy's Labs	28%
Natco Pharma	30.5%
Divis Lab	74.1%

5.3.4 Gross Margin

A look at the financial performance of some of the key players in the AP pharmaceutical cluster reveals that they have earned high gross margins, up to 20-30% for large companies⁵⁴.

5.4 Diamond Analysis



5.4.1 Factor conditions

AP has a large population of English-speaking workers and a significant supply of scientific and technological manpower. The state also has a relatively strong infrastructure, as major cities are well-connected by air (with several airports in the state) road and rail, and several ports⁵⁵. Hyderabad city’s airport is well connected to international destinations. AP also has a relatively stable supply of electricity. Although AP has a number of scientific institutions and pharmaceutical companies, these entities have not partnered together to develop programs, curricula, or incentives for advanced scientific research and innovation. In addition, there is a limited supply of venture capital or other forms of funding to encourage companies to invest in R&D. This has impeded the cluster’s ability to upgrade

beyond bulk or formulation drugs.

5.4.2 Context for Firm Strategy and Rivalry

In 1967, the Indian government set up Indian Drugs and Pharmaceuticals Ltd. (IDPL), a state owned pharmaceutical manufacturer and constructed a major plant in Hyderabad. IDPL was set up to decrease India's dependence on other countries for lifesaving drugs. It has also played a major role in the implementation of major national programs and in the national distribution of drugs. The decision to place an IDPL plant in Hyderabad was an important precursor to the modern pharmaceutical cluster in AP.

The AP government has identified the pharmaceutical cluster as one of its target sectors which makes it eligible for special incentives. These include:

- Access to power cost reimbursements (Rs 0.75 per unit for 5 years): Allows companies to lower their energy costs and accurately forecast part of their future cost structure
- 25% reimbursement of VAT for 5 years: Lowers the cost of operations for companies
- 50% reimbursement for upgrading worker skills: Lowers the cost of companies to upgrade their workforce (particularly valuable for high skill sectors such as pharmaceuticals)

AP has many small and medium-sized enterprises in the cluster, including 266 units manufacturing bulk drugs and 125 manufacturing formulations. State rules and regulations have provided the necessary incentives for these companies to pursue profitable growth: special economic zones have increased infrastructure facilities and export production. They are duty-free enclaves for the purpose of industrial service and trade operations. The SEZ Act (2005) has made additional incentives available to companies operating in the pharmaceutical sector in AP⁵⁶. The Single Window legislation passed in 2002 also facilitated quick project setup times, irrespective of investment size, establishing an effective system of granting clearances and with clear timelines⁵⁷. It is to be noted that drugs exported to

the US or Europe are approved by the regulatory bodies of the importing countries, therefore, companies are forced to produce at a quality that is commensurate with U.S. and European standards.

5.4.3 Related and Supporting Industries

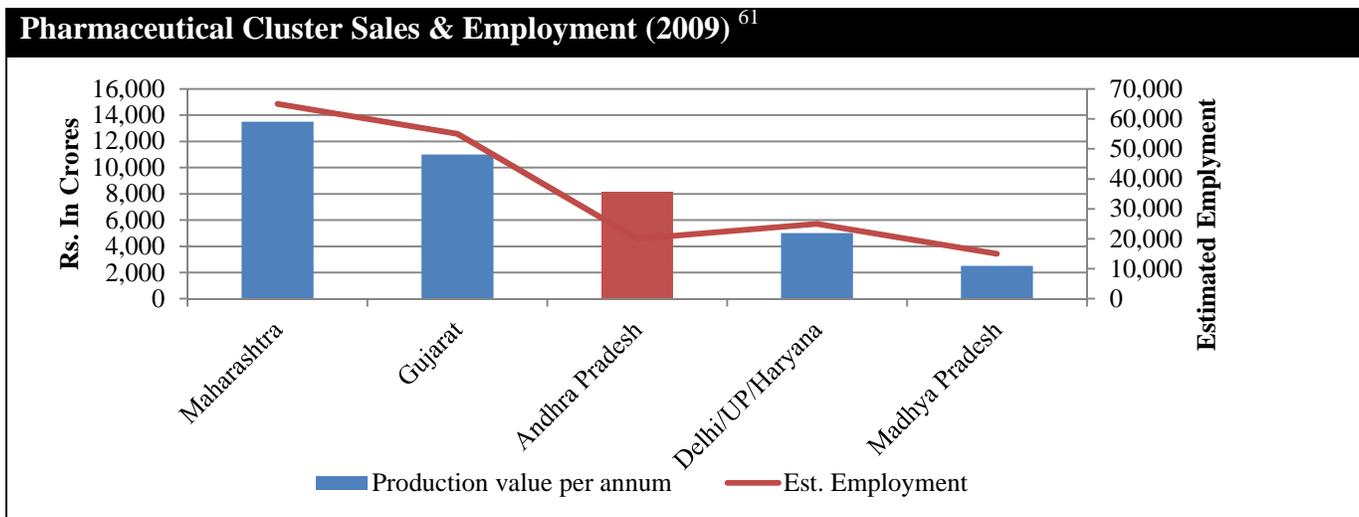
Although direct suppliers of chemical and intermediate products are lacking in sophistication in AP, there are a number of related industries that can help upgrade the quality of the cluster over the long-term: (i) biotechnology, while relatively recent, is growing in AP: Genome Valley is India's first state of the art biotech area providing infrastructure to over 100 biotech companies, and it also contains the ICICI Knowledge Park⁵⁸; (ii) IT is India's largest export cluster, and AP has emerged as one of the leading exporters of software and offshore IT services. Multinational corporations like Microsoft, IBM, Motorola, Oracle, Baan, and Wipro have set up operations in Hyderabad; (iii) the engineering cluster in Andhra Pradesh is well established, producing a range of intermediate and final goods such as foundry and forging items, machine tools, auto components, testing machines, material handling equipment, and components for defense production⁵⁹. The capabilities of the engineering cluster may help produce value machine technology for the pharmaceutical manufacturing process.

5.4.4 Demand Conditions

Like the rest of India, AP's demand for pharmaceutical products is large but less sophisticated when compared with developed markets. Indian consumers are highly price conscious due to the low income per capita and the AP government's expenditure on health per capita is slightly below the Indian average (relative to total expenditure)⁶⁰. Therefore, a majority of the innovation in the industry is expected to occur in developing new ways to produce needed drugs at affordable prices. However, as the AP middle class continues to grow, the demand for next generation pharmaceutical products is expected to grow significantly.

5.5 Competing Pharmaceutical Clusters 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 SEZs⁶² for pharmaceuticals and bio-technology, more than in any other state.

Geographic Distribution of Pharmaceutical Companies⁶³

S. No	State	Number of manufacturing units		Total
		Formulation	Bulk Drugs	
1.	Maharashtra	1,928	1,211	3,139
2.	Gujarat	1,129	397	1,526
3.	West Bengal	694	62	756
4.	AP	528	199	727
5.	Tamil Nadu	472	98	570
6.	Others	3,423	422	3,845
	Total	8,174	2,389	10,563

5.6 Institutions for Collaboration (IFCs)

Several IFCs exist in the pharmaceutical cluster in AP. They exist at both the national and state level and provide support to the industry. However, little data exists demonstrating the effectiveness of these

IFCs and there seems to be a lack of coordination among the public sector supported IFCs and the private sector associations. Some of the key public sector-led IFCs include:

- **District Industries Center⁶⁴** (DIC) - Provides single window service to units in getting approvals. Most cluster firms utilize DIC services including registration, approvals, and incentives.
- **Pharmexcil⁶⁵** - Pharmaceutical Export Promotion Council (Pharmexcil) has been set up for the purpose of export promotion in the pharmaceutical industry.
- **National Institute of Pharmaceutical Education and Research⁶⁶** (NIPER) - Imparts training to entrepreneurs.
- **Research Centers** - Scientific & research institutions such as the Centre for Cellular and Molecular Biology, Indian Institute of Chemical Technology, Centre for DNA Fingerprinting and Diagnostics, and National Institute of Nutrition are working with the pharmaceutical industry.

In the private sector, several industry associations exist. The main objective of these associations is to lobby for favorable government policies. Leading associations include the Organization of Pharmaceutical Producers of India⁶⁷ (OPPI) and Bulk Drugs Manufacturers Association⁶⁸ (BDMA).

6 Recommendations for the Andhra Pradesh Pharmaceutical Cluster

A. Enhance Drug Discovery (Factor Conditions): In order to expand the competitiveness of a pharmaceutical cluster, the private sector must invest extensively in R&D activities to develop new compounds and products. For example, a world class biotech cluster exists in Massachusetts today because the public and private sector was able to partner with leading university and research institutions in Cambridge as well to take advantage abundant venture capital available in the area to finance the expansion of these firms. AP, on the other hand, is focused on providing low-margin bulk drugs to the domestic and export markets. India spends an average of 0.8% of GDP⁶⁹ on R&D, representing one of the lowest levels in the world – levels in Andhra Pradesh are generally in line with country-wide levels. Indian companies have often generated profits by developing low-cost solutions for existing products and selling them into the large domestic market. Therefore, these companies have been unwilling to undertake large-scale R&D projects to develop new pharmaceutical products. Previous efforts by the Government such as the Council for Scientific and Industrial Research were not successful in encouraging the private sector to invest R&D. **Recommendations: (i) eliminate price controls on new pharmaceutical products which would incentivize Indian companies to invest in R&D as at current price caps, they are often unable to recoup high R&D expenses; (ii) create specialized education programs with domestic companies and universities to upgrade quality of labor force; (iii) encourage universities to conduct R&D activities by allowing them to receive royalties in return for new commercial compounds developed (manufacturing, sales and distribution activities to be managed by pharmaceutical companies); (iv) invest in communications infrastructure (underground sea cables), energy supply and transportation networks to fuel productivity (either via PPPs or Government-funded).**

B. Improve Doing Business Index Ranking (CSR): India ranks very poorly in the World Bank's

Doing Business index (#132). It remains challenging for Indian companies to get permits from bureaucracies, property rights are not adequately protected, tax collection is corrupt, customs procedures are cumbersome and there is no systematic method to dealing with bankruptcy. **Recommendations: (i) implement online computerized procedures for property registration, construction permit applications, etc. to make it easier for entrepreneurs to start a new business (as has been implemented in Maharashtra), (ii) simplify the VAT tax system, (iii) continue to enhance e-Government platform to facilitate G2B services.**

C. Increase Cooperation Amongst Pharmaceutical Players vis-à-vis Strengthening Role of IFCs (CSR): Currently, while Indian pharmaceutical companies co-exist in AP, there is limited interaction amongst them with respect to sharing of best practices, coordinating curriculums with domestic research institutions, joint ventures, etc. Leading companies such as Dr. Reddys operate in isolation, and therefore, the cluster, despite the co-location has not been able to upgrade itself. For example, Dr. Reddys has established trade associations and IFCs with other SMEs, but does not involve other major companies such as Aurbindo due to lack of trust – this has served to reduce the effectiveness of the IFCs. Therefore, even though a number of national and state level IFCs exist in AP, they have been unsuccessful in facilitating collaboration amongst firms. In addition, there is limited interaction between the various state clusters (AP, Maharashtra and Gujarat) due to mistrust and lack of coordination mechanisms. **Recommendations: (i) IFC needs to be strengthened via consolidation and expanding the membership, (ii) taking an initiative to build collaboration and knowledge networks between universities, research institute and private players to facilitate R&D and knowledge sharing; (iii) establish forums for timely sharing of industry information, and (iv) reviewing property rights framework to reduce the risk of companies sharing trade details with other industry players via IFCs.**

D. Build Cluster Reputation and Strengthen Export Promotion Bureaus to Attract FDI (CSR):

MNCs have been cautious to invest in the Indian pharmaceutical market due to risks around IP protection, price controls, and a challenging business environment. Compared to other states within India, the corruption level is relatively low in the state of AP (as is common in most South Indian states). As per the World Bank Report Survey, doing business in India 2009 Hyderabad is ranked as 2nd best Metro city in India⁷⁰. However, to be globally competitive, AP has to further lower perception of corruption through simplification of tax policies since complex tax system is one of the main causes of corruption. Also, the Single Window service delivery has helped reduce the bureaucracy within the system by limiting the number of steps required to launch a new venture. AP government officials should focus efforts to attract FDI and encourage MNCs to invest in regional research centers of excellence and manufacturing capacity in AP. **Recommendations: (i) strengthen the role of AP's export promotion bureau to market the state to foreign multinationals as a destination of choice for investment due to low levels of corruption, large pool of skilled labor, sufficient electricity capacity and well-managed SEZs, (ii) make AP a model state for IP protection to alleviate MNC concerns, (iii) provide strict enforcement of quality standards and monitor counterfeit production closely.**

E. Encourage Companies to Invest in a Subset of Therapeutic Areas that Serve Local Needs

(Demand Conditions): There are a few diseases and therapeutic areas that are more prevalent amongst the Indian population when compared with global levels, specifically risks of gastrointestinal disease, diabetes and cardiovascular disease. The Ministry of Health and Family Welfare should work with public sector IFCs, state-level agencies and the private sector to channel their R&D efforts towards therapeutic areas where the demand for products in the local market is relatively more sophisticated. **Recommendations: (i) strengthen the role of AP's export promotion bureau to market the state to**

foreign multinationals as a destination of choice for investment due to low levels of corruption, large pool of skilled labor, sufficient electricity capacity and well-managed SEZs, (ii) make AP a model state for IP protection to alleviate MNC concerns, (iii) provide strict enforcement of quality standards and monitor counterfeit production closely.

F. Enhance Supporting Industries and Related Industries (RSI): A more sophisticated supplier base in the form of the chemicals industry as well as related industries such as the IT services cluster and biotech will help upgrade the competitiveness of AP's pharmaceutical cluster due to spillover benefits of human capital development, improved capital markets, improved infrastructure, and better quality research institutions. **Recommendations: (i) encourage coordination between industries (biotech, pharmaceutical, IT services) by co-locating related companies and setting up forums for interaction, (ii) strengthen the pharmaceutical supplier base by encouraging FDI in the chemicals industry and implementation of best practices to reduce dependence on China ingredients via establishment of trade zones and industrial parks.**

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7.1 Acknowledgement

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7.2 Abbreviations

Abbreviation	Full form
AP	Andhra Pradesh
API	Active Pharmaceutical Ingredients
BPO	Business Process Outsourcing
CAGR	Compound Annual Growth Rate
CRAMS	Contract research and Manufacturing services
CSR	Corporate Social Responsibility
DIC	District Industries Center
DPCO	Drugs Price Control Order
DRL	Dr Reddy's Laboratories Ltd (DRL)
FDA	U S Food and Drug Administration
FDI	Foreign Direct Investment
GSDP	Gross State Domestic Product
IDPL	Indian Drugs and Pharmaceutical Limited
IFC	Institutes for collaboration
IP	Intellectual Property

IT	Information Technology
MNCs	Multinational Companies
NIPER	National Institute of Pharmaceutical Education and Research
OTC	Over the Counter
Pharma	Pharmaceutical
Pharmexcil	Pharmaceutical Export Promotion Council
R&D	Research & Development
SEZ	Special Economic Zone
SME	Small and Medium Enterprises
SOE	State Owned Enterprise
TRIPS	Trade Related Aspects of Intellectual Property Rights
US\$	US Dollar
WTO	World Trade Organization

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