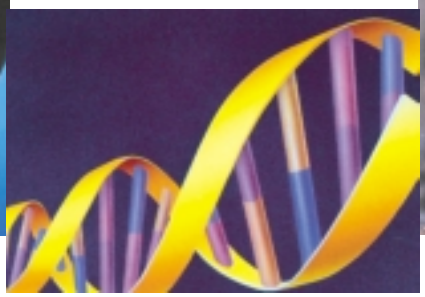
BIOTECHNOLOGY POLICY 2001

ANDHRA PRADESH

Beyond

Tomorrow...

Department of Industries and Commerce
Government of Andhra Pradesh
India

April 2001

Foreword

Andhra Pradesh has set itself an ambitious vision. By 2020, the State will achieve a level of development that will provide its people with varied and realizable opportunities to achieve prosperity and well-being and enjoy a high quality of life.

To attain this level of development, the State will have to embark on a vigorous effort to create rapid economic growth. Technology will play a critical role in accelerating the pace of development in the State. We, therefore, propose to give a thrust to knowledge-based industries such as Information Technology, Biotechnology and Pharmaceuticals. In all these three sectors, Andhra Pradesh has unique proven expertise, commercial success and thus a competitive edge. With the increasing convergence of these technologies, Andhra Pradesh is poised to forge further ahead.

Biotechnology is a frontier technology which has the potential to provide very substantial benefits to society in a wide range of sectors such as agriculture, medical and health, forestry, animal husbandry, environment protection, and improving the quality of products and services.

It is my belief that biotechnology can benefit, in several ways, all sections of the society but more so the very poor - for instance by increasing the availability and enhancing the nutritional value of food grains, by eliminating the use of harmful pesticides, by facilitating the manufacture of cheaper, safer and more effective drugs, by improving the quality of the livestock, by increasing the tree cover in the State and by treating waste material in a safe and eco-friendly manner.

It is, therefore, the intention of the Government of Andhra Pradesh to facilitate the development of biotechnology in the State by creating high quality infrastructure through the strategy of setting up specialized Biotech Parks in different parts of the State, encouraging research activities, developing human resources and establishing links between research institutions, academia and industry. The State Government will create a hassle-free environment for the biotech industry through simplification of procedures and a single window clearance mechanism.

With any new cutting-edge technology, the possible adverse effects need to be monitored and guarded against. Bio-safety, bio-surveillance and bio-ethics will be given due consideration. The protection of Intellectual Property Rights will be an important objective.

I am happy that this Policy has been formulated after wide-ranging consultations with eminent scientists, pioneers in the biotech industry, entrepreneurs, NGO leaders, representatives of user-groups and so on. Together we will work to convert the abundant bio-resources of the State into economic wealth and to sustain the position of Andhra Pradesh as the premier Biotech State in India.

We dedicate this Biotechnology Policy to Dr. Yellapragada Subba Row, a worthy son of Andhra Pradesh and an outstanding bio-chemist, who won international acclaim for his pioneering work in the discovery of aureomycin and related life-saving drugs.

Date: 18-04-2001.

(N.Chandrababu Naidu)
Chief Minister of Andhra Pradesh

CONTENTS

Dedicated to the memory of

Dr. Yellapragada Subba Row,

(1895 - 1948)

a pioneer in the field of Bio-technology

I. Background - The Emerging Biotechnology Scenario

It has been said that the 21st century will belong to biotechnology. Pathbreaking research in this area in recent times has revolutionised the way in which scientists view living matter. The announcement of the completion of the Human Genome Project in June, 2000 and placing the available human gene sequence database in the public domain has opened up exciting new opportunities in the development gene-based technologies.

Biotechnology can be defined in at least two ways. It can mean any technique which uses living organisms or parts of organisms to make or modify products, improve plant or animal productivity or to develop micro-organisms for specific use. This definition encompasses new biological tools as well as ancient uses. A second and narrower definition refers to new "high-end" biotechnology, involving recombinant DNA, cell fusion and novel bio-process engineering techniques such as gene transfer, embryo-manipulation, monoclonal anti-bodies and so on.

Biotechnology involves the integration of such disciplines as biology (plant, animal, microbial), biochemistry, molecular biology, genetics, chemical engineering and computer sciences.

Biotechnology has made profound impact in the fields of health, food, agriculture and environmental protection. It has the potential to provide a wide array of benefits to humanity, including treatment for hitherto incurable diseases, safer, cheaper more effective drugs, more nutritional dairy and agricultural products, more resilient and productive crops and tree species, new sources of renewable energy and safer, more effective treatment of waste.

After years of painstaking research and development in biotechnology, the commercialisation of this frontier technology for the betterment of mankind is poised to grow exponentially. With the help of biotechnology, new products and processes can be introduced to win a competitive edge over the traditional ones in terms of effectiveness, productivity, cost and safety.

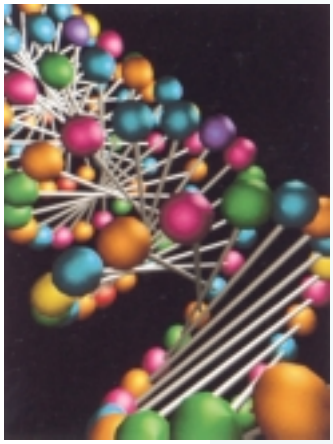
For instance, diseases such as heart disease, cerebral vascular diseases, emphysema, bronchitis, pneumonia, influenza, cancer, diabetes, AIDS, and liver diseases are, increasingly becoming leading causes of death in India. Genetics is involved in all of these. It would be of great interest to medical science to uncover the genetic roots of all these diseases, particularly since medical surveillance or life style changes could certainly reduce the risk considerably. It may be possible in future to take DNA from newborn babies and analyse 50 or more genes for allelic forms that can predispose the infants to many common diseases and provide therapeutic regimes that will circumvent the limitation of the defective genes. Thus, medicine will shift from a reactive mode (curing patients already sick) to a preventive mode (keeping people well) with

specialized treatment based on the individual genotype. Reduced cost of medical treatment can be a great boon to the people, especially in developing countries like India.

Productivity increases in agriculture in India have plateaued in the last a few years and there is apprehension that in future increases in food production will fall behind population growth, if the present conventional breeding technology alone is relied upon. However, biotechnology, in conjunction with the conventional breeding technology, can help in increasing yields dramatically through new plant varieties resistant to environmental stress and pests, in lowering the costs of labour and agriculture inputs, in improving nutritional values of food crops, and in producing environmentally benign weed and insect pest management.

USA, Canada, Argentina, China Australia, Mexico, Spain and S.Africa have made considerable progress in the application of biotechnology in agriculture. The estimated economic benefit from growing genetically improved crops in the USA and Canada was nearly $ 500 million in 1998. This is expected to increase dramatically to $ 6 billion by 2005.

Biotechnology can be a boon especially for India which has a large proportion of its population dependant on agriculture for their livelihood, very low per hectare yields, limited arable land for expansion of cultivation, and increasing demand for food and fibre as a result of increasing population, and a desire for higher standards of living. Biotechnology can also help in arresting the rapid depletion of forest cover and in the treatment of waste.



The “White Revolution” has made India the highest producer of milk in the world. As 80% of the milk comes from small and marginal farmers, any improvement in milk production and livestock would have a tremendous social impact. Biotechnology has a great potential to improve the productivity of the animals through embryo transfer technology (ETT), genetic improvement, vaccines and disease diagnostics. It is well to recall that the world’s first IVF buffalo calf was borne through ETT in India at the National Dairy Research Institute at Karnal.

Endowed with a long coast-line, India has great potential for the development of marine resources and aquaculture. Initial efforts to increase annual production of fish through biotechnological interventions have been very promising, especially in improving per hectare production of carp and tiger prawns and in providing an immuno-stimulant against the white spot disease in prawns.

India has been enthusiastic to develop biotechnology. A separate Department of Biotechnology was set up by Government of India in 1985 to give a boost to the development of biotechnology in the country. Products manufactured by the use of genetic engineering, immunological techniques, cell culture methods and hybridoma technology are being used since the last five years, and local research in these areas has been intensified. Biotech product consumption has been increasing in the last three years. At present, a large number of biotech products consumed in India are produced within the country.

The biotech industry is small, employing about 20,000 people but shows considerable promise to emerge as a sunrise industry which, along with the IT industry, will provide not only large employment opportunities but will also put India on the world map of knowledge-based societies.

Andhra Pradesh - the Competitive Edge:

Rich Bio-resources of the State:

Andhra Pradesh is endowed with rich bio-resources. There are 7 agro-climatic zones across the State, with 19 major food and commercial crops grown in different parts of the State.

There are more than 5000 species of trees and, out of these, 2000 species are flowering trees. About 40 percent of the land is utilised for agriculture and 23 percent of the land is covered by forests in the State.

Agriculture is the lifeline of Andhra Pradesh's economy. The sector contributes over a third of the State's GSDP and provides livelihood for over 70% of its population. It is one of the top three rice-producing States in the country and accounts for about 12% of the nation's rice production. The State has a strong base in horticulture, producing a variety of condiments, fruits and vegetables such as mangoes, citrus fruits, grapes, custard apples, bananas, pineapple, tomatoes and onions. In fact, Andhra Pradesh is the second largest producer of fruits in India and one of the largest vegetable producing States in the country. Andhra Pradesh is a leading producer of a large number of cash crops such as tobacco, oil-seeds, cotton, sugarcane, cashew, mesta, turmeric and chillies. It is the "Seed State" of India, with its progressive farmers taking up production of seed for a variety of crops on behalf of Government and of private seed companies. Floriculture and the cultivation of aromatic and medicinal plants are also rapidly growing sectors. Andhra Pradesh is the second largest producer of silkworm cocoons in the country and sericulture is an important activity in the drought-prone Rayalaseema districts.

Andhra Pradesh is the 7th largest milk-producing State in India. Milk production constitutes 11% of Andhra Pradesh's agriculture economy. In terms of gross value-added, the sector has seen growth at 17% in the last five years. The State has one of the largest breedable bovine population, most of it buffaloes.

Andhra Pradesh has rich fishery potential -inland, marine and brackish water. The State has a coastline of 974 kms and a continental shelf of 33,227 sq.kms, a river course of over 8,500 kms. and large fresh water and brackish water lakes. 40% of India's fish exports are contributed by Andhra Pradesh. Currently, Andhra Pradesh produces around 1.80 lakh tonnes of fish (including shrimp and other species) in the marine sector and 3.87 tonnes in the inland sector (including fresh water prawn).

Thus, abundant and diverse agriculture and forest wealth of the State, large marine resources and cattle population provide tremendous opportunities for the development of the biotech industry.

In Agri-biotech, tissue culture for food crops and ornamental plants has been taken up in several parts of the State with considerable success. There are about half a dozen agri-biotech companies doing flourishing business in this sector in the State.

A Leader in Pharmaceuticals and Medical and Health care:

Traditional Indian forms of medicine such as Ayurveda, Unani and Siddha are practised widely in the State. The wealth of knowledge about the preventive and curative powers of various plants and herbs locally grown can be the base for modern biotechnology.

The Government of Andhra Pradesh believes that the presence of a knowledge-based industry comprising a large number of bulk drug and pharmaceutical companies in the State provides a unique advantage to the State in the field of Pharma Biotech.

The State has a dominant position in the Indian bulk drug and pharmaceutical industry. Roughly one-third of the country's bulk drugs is produced in and around Hyderabad, and the city is rightly considered "The Bulk Drug Capital of India". Andhra Pradesh's pharmaceuticals sector is well-known internationally for its skills in chemical synthesis and process engineering on the one hand, and its commitment to the invention of new molecules on the other, and its speed to market.

With the completion of the Human Genome Project, a large number of bulk drug and pharmaceutical companies are showing keen interest in manufacturing biotech products which could be cheaper, safer and more effective than the products being manufactured at present. For instance, Dr.Reddy's Laboratories, a leading bulk drug and pharmaceutical manufacturing company has set up a separate Biotechnology Division three years ago to manufacture human therapeutic proteins through recombinant DNA technologies and to foray into pharmacogenomics. It is simultaneously developing several molecules in order to offer a basket of value-added products for therapeutic and diagnostic segments. Currently, the company offers diagnostic proteins for HIV infection, therapeutic proteins for use as vaccines, cytokines and anti-virals, and molecules as effective drugs against system i.e. disease . It plans to expand further into the manufacture of recombinant proteins and to secure US-FDA approval to enable it to compete globally. Strong R&D support is provided by Dr. Reddy's Research Foundation.

The presence of a large number of corporate hospitals (Apollo, Medwin, CARE, Medi-Citi, CDR, L.V.Prasad Eye Institute, Indo-Americal Cancer Hospital, Mullapudi Cardiac Centre) and Government hospitals in Hyderabad and facilities for health care education and research will also facilitate clinical trials of biotech products.

A Network of Research and Development Infrastructure:

The State is fortunate to have a large network of research laboratories, such as, the Centre for Cellular and Molecular Biology (CCMB), Centre for DNA Fingerprinting and Diagnostics (CDFD), Indian Institute of Chemical Technology (IICT), International Crop Research Institute for Arid and Semi-Arid Tropics (ICRISAT), the Directorate of Rice Research (DRR) and other specialized agro-research centres of the Indian Council of Agricultural Research (IARI), National Academy of Agricultural Research Management NAARM), National Institute of Nutrition (NIN), Dr. Reddy's Research Foundation (DRF), Aurobindo Research Centre, ICICI Knowledge Park Ltd., Hyderabad Eye Research Foundation, Institute of Genetics and Hospital for Genetic Diseases and the Life Sciences Departments of the University of Hyderabad and of Osmania University.

This existing infrastructure for research will provide the necessary support to the development of biotechnology in the State.

Specialized Institutions as "Centres of Excellence" in Biotechnology:

Centre for Cellular and Molecular Biology : is one of the pre-eminent national laboratories of the Council of Scientific and Industrial Research. It focuses on high quality basic research in the frontier areas of modern biology on research relevant to societal needs, and on application - oriented research towards commercialization.

CCMB provides state of-the-art facilities such as, confocal scanning, fluorescence microscopy, micro array/DNA chips, automated DNA sequencing and proteomics. It also maintains transgenic animal models for human diseases and gene knockouts and a green house for plant molecular biology work. In the area of bio-informatics, it maintains updated databases on nucleic acids and protein sequences, equipped with sequence analytical software and modelling software. CCMB has entered into collaborative programmes with several organizations including contract research for private companies in areas such as DNA fingerprinting, wild life management, genetic descriptions/ID cards for elite germplasm of the Indian rices, molecular characterisation of acanthamoeba keratitis-an eye- infecting protozoan etc. CCMB also imparts training to doctoral and post-doctoral students and conducts short term courses and workshops on specialized topics.

Centre for DNA Fingerprinting and Diagnostics (CDFD): was set up with the primary objective of providing DNA typing and analysis of exhibits referred to it by crime investing agencies. Another important service component of CDFD is molecular diagnostics. The molecular basis of various genetic diseases is sought to be established by consolidating all the three laboratory-based approaches - the biochemical, cytogenetic and molecular. The diagnostic group at CDFD reports on suspected chromosomal abnormalities and offers vital diagnostic tests in instances of high-risk pregnancies. The biochemical screening of new borns for inborn errors for metabolism is now being done at CDFD. The European Molecular Biology Network (EMBNet) mode at CDFD

represents one of the only two nodes outside Europe. More than 25 data banks have been set up on CDFD web servers which can be accessed over the internet. The bioinformatics facility at CDFD is well geared in terms of hardware and software to address computational issues in the post-genomics scenario. CDFD also conducts research at the frontiers of modern biology which includes silk worm genetics, computational and functional biology, gene expression, genetics of bacterial stress, molecular epidemiology, mechanism of intervention in the disease process and molecular oncology. Its collaboration with the Hyderabad Eye Research Foundation has led to the identification of mutations in human genes responsible for certain eye diseases and methods to manage them. Its current efforts in collaboration with colleagues at CDC Atlanta, GA USA, involve testing a candidate malaria vaccine, based on a multiple gene construct.

Laboratory for the Conservation of Endangered Species (Lacones) is being set up near the Nehru Zoological Park for which the Government of A.P. has provided 5 acres of land. This is a unique project in the world funded by Department of Biotechnology, and the Central Zoo Authority of Government of India in collaboration with CCMB, Nehru Zoological Park and the Forest Department of the Government of Andhra Pradesh. In this centre, high-tech research of biotechnological nature such as, genetic characterisation, strategies for breeding, sperm and egg banks of endangered species, artificial insemination and in-vitro fertilization and eventually cloning of the endangered animals will be undertaken. This project has national and international significance in terms of maintaining biodiversity.

National Institute of Nutrition (NIN): This Flagship institution of the Indian Council of Medical Research has not only conducted R&D programmes in human nutrition but has also been involved in international studies to improve the health of children, pregnant and lactating mothers and others, and to validate the benefits of traditional Indian spices and condiments as health aids and beneficiaries. NIN has the best animal house in the country, aided by the DBT, where both in-house and collaborative drug trials are successfully held. Its special strain of obese mice has proved useful in studying the pathological effects of overweight, and ways to control and combat its ill-effects.

CCMB, CDFD and NIN offer Ph.D. degree programmes recognised by Osmania, University of Hyderabad and Jawaharlal Nehru University, New Delhi.

Availability of Scientific and Technical Manpower:

In addition to the above research institutions, Andhra Pradesh has 9 Universities located in different parts of the State viz., Osmania University, Jawaharlal Nehru Technological University, Acharya N.G.Ranga Agricultural University, Kakatiya University, Nagarjuna University, Andhra University, Sri Venkateswara University, Sri Krishna Devaraya University and Sri Padmavati Mahila Visvavidyalayam which offer undergraduate and post-graduate level courses in biotechnology at present. Every year about 900 students at the graduate level and 200 students at the post-

graduate level pass out of these institutions. In addition, the University of Hyderabad, Acharya N.G.Ranga Agricultural University, Medical Institutes such as NIMS and SVIMS, the NTR Health University and their centres have R and D facilities in various areas of biotechnology.

Thus, Andhra Pradesh has a large pool of scientific and technical manpower which will provide the required support to the knowledge-based industries in the State.

Convergence of Technologies:

The State has made rapid strides in the development of Information Technology in recent years. The active presence in Hyderabad of global players such as, Microsoft, Oracle, PSInet, Portalplayer, Infosys, Wipro and Satyam have put the State in the forefront of the IT revolution in the country. With the convergence of all the three knowledge-based sectors of Information Technology, Biotechnology and Pharma Technology, the State is poised to make rapid strides on the strength of synergies existing among them.

Recently, six Bioinformatics Centres have been set up through private initiative in Hyderabad viz. Tata Consultancy Services, GVK Bio Sciences Pvt. Ltd., Xpert Global Tech. Ltd., Satyam, OCIMUM Pvt. Ltd. and Cerebral Info Builders Pvt. Ltd.

Existence of a Critical Mass for the Biotech Industry:

Andhra Pradesh has several pioneers in Biotech industry such as, Shanta Biotechniques Private Ltd., Bharat Biotech International Ltd., Biological E.Ltd., Indian Immunologicals Ltd., Krebs Biochemicals, Jupiter Orga, Dr. Reddy's Laboratories, Godrej Plant Biotech Ltd., AG.Biotech Laboratories (India) Ltd., Biochemical and Synthetics Products Private Ltd. Biotissues Pvt. Lab. Ltd, Classic Biotech and Exports Ltd, Fortune Biotech Ltd, Harita Biotech and Plantations, Mericlone Bioteck Private Ltd., Metchnikoff Biosystems Pvt. Ltd., Nuziveedu Seeds Ltd., Prabhat Agribiotech Ltd., Sun Floriculture Biotech Ltd., Transgene Biotek Ltd., Vermigreen Bio-fertilizers, Godavari Fertilizers and Chemicals Ltd., Viswa Mitra Bio Agro Ltd., amongst others, who have created a critical mass for the industry.

There are at present, only two companies in India which have successfully commercialized biotech products based on recombinant DNA technologies and both are located in Hyderabad.

Shantha Biotechnics Pvt. Ltd., founded in 1993 by Mr.K.Varaprasad Reddy is the largest biotechnology company in India in the private sector and was successful in launching India's first genetically engineered human health care product - a vaccine for Hepatitis B with recombinant DNA technology under the brand name "Shanvac B". The company is involved in the development of major generics like interferon alpha, insulin, streptokinase, Granulocyte Colony Stimulating Factor (GCSF), diagnostic and therapeutic antibodies for various diseases, new vaccines against Hepatitis - C and Hepatitis E viruses, new generation vaccines against Hepatitis - B virus, the development of new formulations and drug delivery systems, and the molecular cloning and

expression of native genes. It has a state-of-the art R and D facility near Hyderabad with highly qualified scientific personnel. The company has gone global in August, 2000 by establishing a subsidiary in Delaware, USA and by entering into a strategic alliance with Crop.Tech.Inc. USA for providing cloning technologies. It was awarded the First National Technology Award for Successful Development and Commercialization of Indigenous Technology and the DSIR Award for Best R&D Efforts in Industry by Govt. of India.

Bharat Biotech International Ltd. was set up by Dr. Krishna Ella, a scientist - entrepreneur with the aim of pursuing pioneering research in health care through genetic engineering and of producing health care products for diseases endemic to India and the South East Asian Region. It was a pioneer in producing a Hepatitis-B vaccine based on recombinant DNA technology under the brand name of REVAC-B. It is the first vaccine in the world to be produced without caesium chloride, a toxic metal. It is the second largest biotech facility for the manufacture of Hepatitis B in the world with a capacity of 100 million doses per annum. It has a state-of-the art multi-product contract manufacturing, formulation and filling plant for biotechnology products. The company's current research activities cover a third generation Hepatitis - B vaccine in collaboration with the Indian Institute of Science, Streptokinase, human insulin and Vascular Endothelial Growth Factor (VEGF). The company won the National Award in 1999 for Best R and D efforts from Government of India. It is the largest biotech facility in India confirming to the standards of WHO, USFDA and UKMCA.

The State has many talented entrepreneurs who can follow the lead given by these pioneers and can set up successful biotech firms, given the right environment and encouragement. For a knowledge-based industry like biotechnology, close networking between research, academic institutions and industry is critical for success. Hyderabad is eminently suited for such a technology-driven industry in view of the large number of research and academic institutions with strength in biotechnology located in this city.

II. Objectives of the Biotech Policy

Government of Andhra Pradesh has identified the biotech sector as one of the "Engines of Growth" in the Vision 2020 document. The Government will leverage the existing strengths of the State for rapid commercialisation of biotechnology to produce innovative biotech products and services in a wide range of areas.

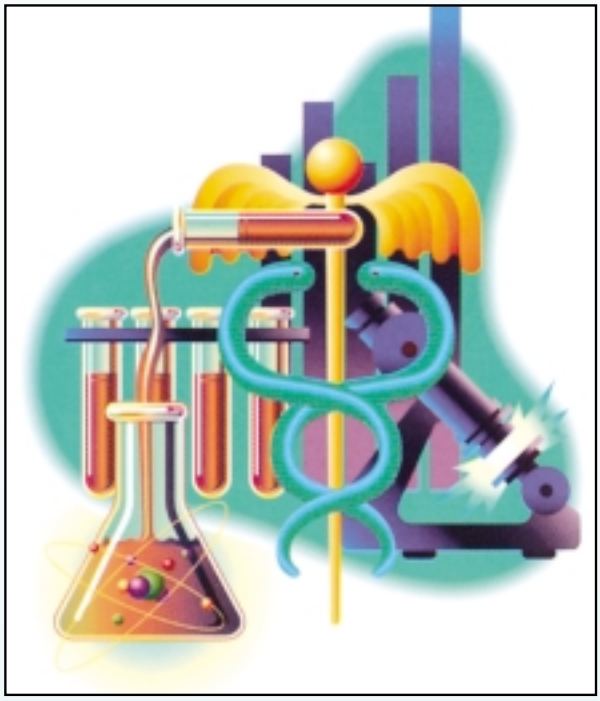
The Government of Andhra Pradesh recognizes the pioneering efforts made by a few entrepreneurs in setting up highly successful biotech companies such as, Shanta Biotechnics, Ltd. and Bharat Biotech Ltd. which have, in a very short span of time, gained world-wide recognition and put Andhra Pradesh in the forefront of the Biotech revolution in India. The Government envisages a very active role of the private sector in the development of the biotechnology industry. The Government would act as a facilitator and a catalyst. It has felt the need for a well-defined policy to forge a Private-Public Partnership in the development of biotechnology in the State.

It is expected that the large number of scientists from Andhra Pradesh, who are at present engaged in research, academics or manufacturing in the field of biotechnology in USA and other developed countries will play catalytic and enabling role in developing biotechnology in the State, given the right environment, as was the case with Information Technology.

The objectives of the Biotech Policy are:

- to take up a detailed inventory of the bio-resources in the State with the help of Universities, research institutions, NGOs and private agencies.
- to promote conservation of bio-diversity and sustainable exploitation of bio-resources.
- to create a congenial environment for encouraging R and D in biotechnology and allied fields through the development of infrastructure and through appropriate incentives and regulatory framework for research
- to develop high quality infrastructure with the required support services for manufacturing units by setting up specialized Biotech Parks in various parts of the State.
- to provide special incentives to the biotech industry and related sectors
- to focus on human resource development in the area
- to create an enabling environment for the growth of the biotech industry, especially the simplification of procedures for getting clearances for the commercialization of new biotech products and for the use of laboratory animals for drug discovery

- to develop bioinformatics, leveraging the State's existing strength in Information Technology for the development of biotechnology
- to facilitate the flow of venture capital funds and bank credit to biotech companies
- to address issues such as Intellectual Property Rights, Biosafety, Bio-surveillance and Bio-ethics.



III. The Biotech Industry - Problems and Prospects

Complex regulatory procedures, lack of good quality infrastructure, rigid labour laws, the dearth of scientific personnel with experience in manufacturing biotech products, ineffective laws relating to Intellectual Property Rights and their enforcement through the Courts and complicated clearance procedures for commercialization of new biotech products are some of the problems faced by the nascent biotech industry in the State. Several scientists working at public and private research institutions have expressed deep concern about the complicated rules for the use of laboratory animals for drug discovery.

In interactions with the pioneers in the field, it has been emphatically stated by them that these problems could be overcome by the industry if the Government puts in place industry-friendly policies and simplifies the procedures for various clearances required for commercializaing new biotech products or services.

IV. Strategies

Thrust Areas:

Based on industry analysis of the biotech sector and inputs from experts, the following short list of focus areas has been arrived at:

- Diagnostics
- Therapeutics
- Pharmacogenomics
- Bioinformatics
- Agriculture biotechnology
- Industrial biotechnology
- Inputs to the industry (hardware suppliers - instrumentation and chemicals)
- Marine biotechnology
- Forest-and Environment-focused biotechnology
- Contract research in all areas of biotechnology and related areas

V. Encouraging R and D

It is believed that the Indian biotech industry will initially focus on Research and Development. Indian capability in knowledge-based industries is now well-recognized and several large multi-national companies have shown interest in setting up their biotech R and D centres in India in view of the availability of good quality scientific and technical manpower at reasonable cost. There is also a tremendous scope for research institutions and Universities to take up contract research on behalf of multi-national companies and research-driven domestic companies.

The Government of Andhra Pradesh has assisted ICICI, a leading financial institution in the country, to set up the ICICI Knowledge Park at Turkapalli village near Hyderabad. The Park provides ready-to-use laboratories on lease basis to companies and provides support services. The first module with 10,000 sq. feet of built-up space is ready for occupation. It is expected that 7 more modules will be created in the near future. Developed land is also available on long-term lease basis to private companies to set up their own independent research facilities.

The Knowledge-Park has been declared as a Scientific and Industrial Research Organisation (SIRO) by the Department of Science and Technology of Government of India. A proposal has been made to recognize the client companies located in the Park also as SIRO , which is under consideration of the DSIR, Ministry of Science and Technology. An arrangement has been reached between the Knowledge Park Authorities and the Customs Authorities for a simplified, quick and hassle-free procedure for clearing imports by the clients of the Park intended for research and also for exports of biotech products by them. The proposed Biotech Park in Turkapally will have an organic relationship with the ICICI-Knowledge Park, in terms of Research & Development and related activities.

The Government of Andhra Pradesh will encourage the setting up of more such Knowledge Parks in other parts of the State and also the setting up of private R&D facilities. The Government of Andhra Pradesh will offer special one-time grants for setting up R and D facilities in the Universities in the area of biotechnology.

The Government of Andhra Pradesh will encourage the Universities and State Government departmental laboratories to take up contract research in the field of biotechnology on behalf of national and multi-national private organizations/companies and on behalf of public agencies.

VI. Infrastructure Development

The Government of Andhra Pradesh intends to provide high quality infrastructure at a reasonable cost with integrated services to biotech manufacturing units by setting up a series of Biotech Parks throughout the State.

The first such Park will be set up at Turkapalli village, Shamirpet Mandal, Ranga Reddy District, over approximately 150 acres of Government land, adjacent to the ICICI Knowledge Park. The Park will be set up as a joint venture project with a private promoter who will contribute to the equity of the project and will be responsible for designing, constructing, financing, marketing and maintaining the Park. The Park will aim to attract domestic and overseas firms.

In pursuance of the new Industrial Policy 2001-2005, the Government of Andhra Pradesh will provide the basic infrastructure to the border of the Biotech Park viz., piped water supply, electricity substation, telecommunications with fibre optic connectivity, and approach road. There will be no power cuts in this Park and individual units will be permitted captive power generation.

The Government of Andhra Pradesh will seek the support of Government of India in setting up a **National Resource Centre** which will provide common facilities to the biotech companies and also incubators. The Government of Andhra Pradesh will also facilitate and support the setting up of specialized animal house facilities for laboratory experimentation, breeding of experimental animal models and development of genetically manipulated/modified animal models in the Biotech Park.

The Biotech Park will enter into an arrangement with the ICICI Knowledge Park for the sharing of infrastructure and the Parks together will provide " Idea to Commercialisation" services to the clients. In the first phase, the focus in this Park will be on therapeutics, diagnostics and industrial biotech.

The Biotech Park aims to provide world-class services to the clients in terms of

- State-of-the-art infrastructure
- One-Stop-Services
- Quality products and services at competitive cost
- Database on availability of skilled professionals
- Networking between research and academic institutions and industry

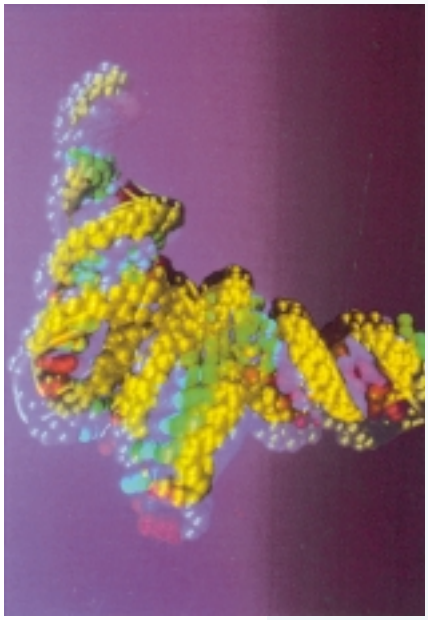
The advantages of the Park are visualized as:

- Provide a thrust to areas of prioritized industry segments

- Help achieve regional and global leadership in the chosen areas through sharp focus
- Allow for midstream corrections in the subsequent phases of development
- Reduce the capital outlay for entrepreneurs
- Improve the rate of return on investment

To make the Park attractive to Biotech companies, the Government of Andhra Pradesh will facilitate the following through its own efforts or by soliciting the support of appropriate agencies/ departments of the Government of India and international development agencies.

- Government of Andhra Pradesh will set up an administrative mechanism of a "single window" to facilitale quick clearances/approvals under various statutes and regulations of the State Government and the Govt. of India for the Park-users.



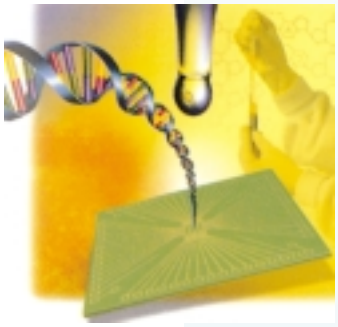
- Assist the private joint venture partner to attract some well reputed service/ utility providers to establish their units in the Park to provide certain specialized services to the Park-users on a commercial basis such as de-ionized double distilled water, bioinformatics, instrumentation and testing facilities, Animal House etc.,
- Assist the private joint venture partner in getting grants/equity/soft loans from Government of India, International Development agencies, multinational agencies.
- Get a Rapid Environment Impact Assessment Study done for the Park area through the Environment Protection, Training and Research Institute (EPTRI) and facilitate pollution clearances for individual units located in the Park through the assistance of EPTRI.
- Declare the 25-Kilometres belt around the Park as a "Pollution-Free-Zone" by banning the setting up of certain polluting industries in this Zone

Government of Andhra Pradesh declares the area of approximately 600 sq. kilometres covering the mandals of Shamirpet, Medchal, Keesra and Uppal in Ranga Reddy District as the **"Genome Valley"** in which biotech activities will be encouraged and promoted. The area has developed as a natural cluster for biotech research, training and manufacturing activities with the following institutions and companies located here. Biotech Park and Knowledge Park and Bharat Biotech in Turkapalli village, Shamirpet mandal, Medi Citi, Shanta Biotechnics, Godrej Plant Biotech and Metchinikoff Biosystems near Medchal town, Satyam, Forest Research Centre near Doolapalli, Nuzeevedu Seed Co. at Kompally in Medchal Mandal, Indian Institute of Chemical Technology (IICT), National Institute for Nutrition (NIN), Centre for Cellular and Molecular Biology (CCMB), the Centre for DNA Fingerprinting and Diagnostics, Osmania University in Uppal.

This Genome Valley near Hyderabad will foster Biotech activities that promote economic development through the development and exchange of knowledge and technologies. It will provide an investor-friendly environment that will attract large corporations to set their Biotech R&D and manufacturing units here and will also, nurture start-up companies. It will provide not only high quality infrastructure for biotechnology such as superior telecommunications, uninterrupted power, well developed road network, assured water supply and attractive housing and recreation areas, but also specialized facilities and services such as training and research institutes, bioinformatic centres, input suppliers.

The Government of Andhra Pradesh will set up similar Corridors and Biotech Parks with a focus on agriculture, horticulture, marine, animal husbandry, forestry and environment protection in other parts of the State.

Agri-biotechnology will be given a thrust in the districts of Guntur, Krishna, West Godavari and East Godavari using the facilities available at the Lam Farm in Guntur district, Maruturu Farm (for rice research) and Kovvur Research Centre (for vegetables, tubers and bananas) in West Godavari district.



Similarly, biotechnology for the development of sericulture and of oilseeds cultivation, will be encouraged in the Rayalaseema region, using the facilities at the Sri Krishnadevaraya University, Ananthapur , the Sericulture Research Centre at Hindupur, the agriculture research stations of ANGRAU at Kadiri Nandyal, Tirupati, Chittoor and the Directorate of Oilseeds Research of ICAR at Hyderabad.

Marine biotechnology will be developed in the Visakhapatnam-Kakinada coastal belt using the training and R&D facilities set up by the Indian Council for Agriculture Research (ICAR) at Visakhapatnam viz., the Central Marine Fisheries Research Institute, the Central Institute of Fisheries Technology and the Central Institute of Fisheries Education and the facilities for training set up by Govt. of Andhra Pradesh at Kakinada viz. State Institute of Fisheries Technology and the training facility of the Andhra University at Visakhapatnam, which has a well-established Marine Biology Department.

Vision 2020 has identified the Fisheries sector as one of the Engines of Growth. It is envisaged that by 2020, Andhra Pradesh will have a thriving fisheries sector. Fish production will be four times its current size, reaching over 10 lakh tonnes a year. The sector will provide nutritional food to the people and will have enough surplus for exports. Biotechnology will be used to enhance production and productivity.

There is tremendous scope for using biotechnology in disease diagnosis in animals and in the production of animal vaccines and hormones. The State Government will utilize the facility at the Veterinary Biological Research Institute and Indian Immunoligicals Ltd., at Hyderabad for taking up

research in these areas. Private companies will also be encouraged to develop biotech animal vaccines, hormones, monoclonal antibodies and diagnostic kits. Biotechnology can also be used for the development of high yield fodder seeds and for ova transplantation and multiple ovulation. For these activities necessary support will be given for research and extension.

The dairy sector has also been identified as one of the “Engines of Growth” in the Vision 2020. It is envisaged that Andhra Pradesh will be among the top three producers of milk and milk products in India by 2020. It is felt that biotechnology can provide several opportunities to increase yields and improve the health of the cattle and thereby to achieve the goal laid in the Vision document.

The development and propagation of new and improved varieties of tree species will be taken up in the Telengana region with the support of the Forest Department’s research stations at Dhoolapally in Ranga Reddy district, at Mulug in Medak district, Achuthapuram in Khammam district and Warangal and research stations under the AP-Netherland Biotech Project, in order to increase the tree cover in the region.

Plant cell and tissue technology will be used to develop horticulture in the State with a thrust on clonal propagation, disease elimination, germplasm exchange, gene transfer by wide hybridization, molecular genetical engineering, variant selection including somo-clonal variation Initially, the new techniques will be applied to crops such as mango, banana, citrus and turmeric and to some ornamental crops.

VII. Incentives

Sales Tax:

- Keeping in view the special difficulties and risks involved in commercialising cutting-edge technologies in the field of biotechnology, Government of A.P. has fixed a nominal sales tax of 1% for "high-end" biotech products manufactured by units located in the Biotech Park in Turkapalli village, Shamirpet mandal, Ranga Reddy district. This sales tax rate will be applicable only for a period of 7 years from the date of commencement of commercial production of a biotech unit, and will be extended only to those units which go into commercial production on or before March 31st, 2006. The cut-off date for this concessional rate is 31st March, 2010, beyond which date no new unit in this Park will be extended this incentive. The Department of Science and Technology, Government of India will notify products which do not fall in the category of 'high end' from time to time.

- Similar incentives will be offered to units in other Biotech Parks that may be set up in the State.
- Government of Andhra Pradesh will introduce a separate entry for biotech products in the schedule of sales tax
- Govt. of Andhra Pradesh will propose to Govt. of India that high-end biotech products should be exempt from all taxes for a period of 10 years. The definition of high-end biotech products will be provided by the Department of Science and Technology, Govt. of India.

Land for Biotech Parks/Activities:

- Government of Andhra Pradesh will provide, wherever possible, government land on lease or as equity to other Biotech Parks, if the site is otherwise found suitable for such projects.
- In order to encourage the setting up of bioinformatic centres, Government of Andhra Pradesh will offer a rebate in the cost of government land allotted to a bioinformatics company at Rs. 20,000 (Twenty thousand only) per job created, subject to the following conditions:

i) The rebate shall be applicable only in respect of lands allotted by Government/AP IIC with prospective effect

ii) The rebate shall be restricted to Rs. 20,000 per job created for persons specializing in Bio-informatics or the cost of the bare land (excluding development charges/cost), whichever

is less. A maximum of 1 acre of government land will be allotted to any company for setting up a bioinformatics centre.

- Bioinformatic centres will be permitted to be established without any locational restrictions. They can be established in residential, commercial or industrial zones
- Companies setting up Bioinformatics Centres in the Genome Valley will get a rebate of Rs. 30,000 per job created, subject to the value of a maximum of 2 acres of government land and a 100% exemption from registration and stamp duties. Similar incentive will be provided to the Bioinformatic units to be set up in Biotech Parks.

Exemption from Power Cuts:

- The biotech industry is exempt from the purview of statutory power cuts
- Industrial power tariff (and all other admissible incentives and concessions for industry) will be applicable to the biotech industry.

Labour Concessions:

- General permission will be accorded to run a three-shift operation to the biotech industry (subject to Government of India concurrence)

- Allow women to work in the 3rd shift, subject to certain safety norms (subject to Government of India concurrence).
- A system of self-certification will be introduced for the biotech industry under various Factories' and Labour Acts.
- Permit flexibility in the opening and closing times and in the weekly holiday of a biotech unit by amending relevant provisions of the A.P. Shops and Establishment Act.
- Exempt biotech units from the provisions of Contract Labour Act 1970, in so far as non-core activities are concerned (with concurrence of Government of India)
- Delegate all or some of the powers of the Labour Commissioner to designated officers to tackle the labour problems efficiently and promptly in Biotech Parks.
- Set up exclusive Special Industrial Tribunals for Biotech Parks to give top priority to the settlement of disputes that may arise in units located in the Biotech parks.

Land and Grants for Training Institutes:

Government will allot government land either free of cost, or at a concessional rate and give grants for capital expenditure to Institutes of Training in the field of biotechnology and related areas on a case by case basis in the Genome Valley. Training and extension for farmers and technicians in the area of biotechnology will also be taken up through such institutions and users of ICICI-Knowledge Park.

Land for Housing :

Government will provide Government land at concessional rate, wherever suitable land is available for developing housing and recreation facilities for personnel working in Biotech field in designated areas in and around Genome Valley.

Mega Projects:

Special incentives will be offered, on a case by case basis, to mega projects with an investment of more than Rs. 50 crores in a new company, or in the expansion of an existing company, which provide employment to more than 250 persons technically qualified in the area of biotechnology or allied fields.

VIII. Human Resource Development

Keeping in view the critical role played by scientific and technical manpower in the growth of a knowledge-driven industry such as biotechnology, Government of Andhra Pradesh will encourage the study of biotechnology and bio-informatics at the graduate and post-graduate levels throughout the State. A Post-graduate course in biotechnology has already been introduced in the University of Hyderabad, which is ranked one amongst the five top Universities in India by UGC. Post-Gradaute courses in biotechnology have been introduced also by 9 State Universities. These centres will be further strengthened.

Universities will be offered special one-time grants for setting up infrastructure for R & D in the area of biotechnology and for starting graduate and post-graduate full-time programmes in biotechnology and bio-informatics.

Efforts will be made to establish collaborations in teaching and research between Universities in Andhra Pradesh and leading Universities across the world in the field of biotechnology.

The Institute of Public Enterprises located in Osmania University will offer a two-year Postgraduate course in the management of biotech companies. It will be a Management Course with a focus on creating entrepreneurs in the field of biotechnology.

The Administrative Staff College of India, Hyderabad will introduce short-term and long-term courses in Bioinformatics. It will also introduce courses in management of biotech companies with a focus on creating entrepreneurs in the field of biotechnology.

The National Resource Centre at the Biotech Park and the ICICI Knowledge Park at Turkapalli will organize seminars and workshops in biotechnology. This will facilitate knowledge-sharing to keep local companies and scientists aware of the latest developments world-wide, in Biotechnology.

The ICICI and other financial institutions and some public institutions will be approached to set up an Institute of Bioinformatics and Applied Biotechnology (IBAB) in the Genome Valley. The Institute is expected to run along the lines of CNRS France or the Howard Hughes Foundation, U.S.A. It will facilitate to research and development activities in the field of bioinformatics and other related areas, undertake short-term training programmes and set up incubators for new entrepreneurs. The institute will collaborate with institutes such as LVPEI, NIMS, NIN, IICT, CCMB, CDFD, IIIT and the University of Hyderabad, and will facilitate the setting up of super computing facilities for training and development activities with access to all kinds of software and data banks around the world.

IX. Creating An Enabling Environment

A separate Department of Biotechnology will be set up in the Government of Andhra Pradesh, headed by an eminent bioscientists/biotechnologists, with the status that of a Principal Secretary/ Secretary. It will be responsible for the promotion and development of biotechnology in the State and will be a single-point contact for all entrepreneurs wanting to set up biotech manufacturing or service units and for those who wish to set up research or training institutions in the field of biotechnology. It will address issues such as bio-safety, bio-surveillance, bio-ethics and intellectual property rights in the field of biotechnology. It will co-ordinate the efforts of various departments of the State Government such as Agriculture, Industry and Commerce, Medical and Health, Animal Husbandry, Information Technology, Fisheries, Environment and Forests, Education, Energy and Revenue in promoting biotechnology and will also co-ordinate with the respective Ministries of Government of India and various specialized agencies. It will be the Secretariat for the Andhra Pradesh Biotechnology Development Council.

The Government of Andhra Pradesh will ensure that the procedures for getting approvals and clearances for the commercialization of new biotech products will be simplified, if necessary, by taking up the issue with the departments concerned of Government of India. It will also seek the simplification of rules regarding the use of laboratory animals for drug discovery.

Government of A.P. has set up a Biotechnology Advisory Committee with Dr. Manju Sharma, Secretary, Department of Biotechnology, Government of India as Patron and eminent scientists and experts, Dr.D. Balasubramanian, Dr. M.V. Rao, Dr.A. Venkateswarlu, Dr. Lalji Singh and Dr. Seyed Hasnain, as members to advise the Government of Andhra Pradesh on the promotion and development of biotechnology in the State. The representatives of the Biotech Park joint venture partner and the consultants M/s. Ernst & Young are also members of this Committee. The terms of reference of this Committee are:

1. to advise the Biotech Park Joint Venture Company on the type of biotech activities that may be permissible in the Park.
2. to advise the Biotech Park Joint Venture Company on the type of facilities that should be provided in the Park.
3. to advise the Biotech Park Joint Venture Company on technology issues regarding individual investments that may be referred to them by the Joint Venture Company.

4. to advise the Biotech Park Joint Venture Company and Government of A.P. on Bio-safety issues.
5. to advise the Biotech Park Joint Venture Company and Government of A.P. on issues relating to Intellectual Property Rights.
6. to advise the Government of A.P. on issues relating generally to the development of biotechnology in the State.
7. to constitute Sub-Committees or Technology Resource Group of experts in order to promote Biotechnology / commercialization of Biotechnology in the State

Government of A.P. will set up the Andhra Pradesh Biotechnology Development Council, with the Chief Minister as Chairman and Ministers incharge of Industry, Agriculture, Environment and Forestry, Animal Husbandry and Fisheries, Medical and Health, Energy, Information Technology, Education and Revenue as members. Members of the Biotechnology Advisory Commiittee, besides eminent scientists, experts, industrialists and consultants in the field of biotechnology will also be members of the council.

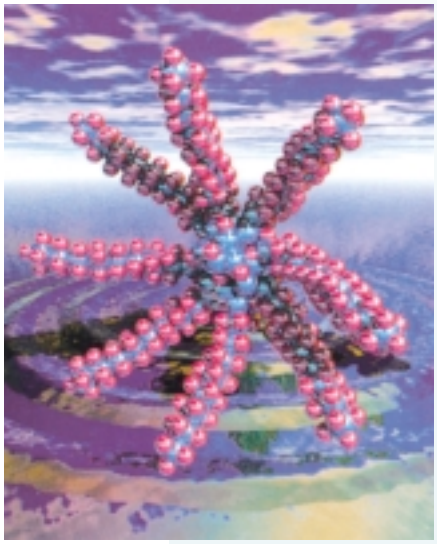
The Council will review and monitor the development of biotechnology in the State and will lay down policy guidelines in all matters relating to biotechnology. The Council will address the issue of creating an awareness amongst the potential users/clients of biotechnology products and services about the benefits of the new technologies and the safeguards to be put in place.

X. Funding Biotech Activities

APIDC Venture Capital Limited, a joint venture between the A.P. Industrial Development Corporation and Dynam Venture East of USA, which has been providing venture capital to biotech start-ups since early 1990's, will allocate a major part of its next fund to the biotech sector, including bioinformatics, with preference to Park-users. This fund will invest in start-ups and will be managed by a group of professionals.

Other Venture Capital Funds and Banks such as Canbank Venture Capital, Gujarat Venture Capital, IDBI Venture Capital, IFB Venture Capital, IFCI Venture Capital, Industrial Venture Capital, SICOB Venture Fund, SIDBI Ventures, UTI Ventures, Alliance Venture, Chrysalis Capital, Barings Pvt. Equity, Global Tech Ventures, HSBC Private Equity, ICF Ventures, Indus Venture Management, AIG Capital, Alchemy Ventures, Bank of America, Carlyle Fund, CDC Advisors, Chase Capital, Citibank Pvt. Equity, Deutsche Bank, GE Capital, ICICI Ventures, IFC, Washington D.C. , IL & FS Venture Corporation, Ind. Asia Fund, Kotak Mahindra, Morgan Stanley, Walden Shroeders, Warburg Pincus and others will be encouraged to operate in Andhra Pradesh.

The Rabobank (India) Private Limited has been appointed as the Strategic banker to the Biotech Park and the banker of first preference for the clients in the Park.



To promote biotech activities in the State, Government of A.P. will set up a Biotechnology Development Fund, with an initial corpus of Rs.50 crores. Henceforth, sales tax paid by all biotech companies and the returns on equity held by the State Government in the Biotech Parks and any other development funds (such as, grants or soft loans from International Development Agencies, bilateral assistance from other countries, assistance from Govt. of India) will be invested in this Fund. The Fund will be managed by the Andhra Pradesh Biotechnology Development Council under the Chairmanship of the Chief Minister. The fund will be utilized for developing biotechnology in the State, ensuring due priority for the units to be set up in Biotech Parks.

XI. Protecting Intellectual Property Rights

Keeping in view the importance of Intellectual Property Rights in spurring research and innovation in a Knowledge Society, Government of Andhra Pradesh will play a proactive role in creating an awareness throughout the State. The Government of Andhra Pradesh, in collaboration with the Technology Information, Forecasting and Assessment Council (TIFAC), an autonomous agency of the Department of Science and Technology of the Government of India and the Confederation of Indian Industry, has set up the Andhra Pradesh Technology Development Centre (APTDC) which has, as some of its objectives, the development of a data base on world wide patents, providing patent search facilities for local scientists and entrepreneurs and creating an awareness of Intellectual Property Rights in Andhra Pradesh and an innovative mind set amongst its people.

Osmania University has introduced a Post-Graduate Diploma course in Intellectual Property Rights in the Law College for law students and for industry-sponsored candidates. The Government of A.P. will encourage the introduction of similar post-graduate courses in the Law faculties of other Universities and in the National Law School. The Government of A.P. will recommend the introduction of one optional paper on Intellectual Property Rights in the graduate courses in Law, in Life Sciences and in Engineering throughout the State.

The APTDC will prepare a panel of qualified Patent Attorneys so as to assist scientists and entrepreneurs in defending their patent rights in courts of Law. The APTDC will organize seminars and workshops for persons from different walks of life like industrialists, lawyers, police officials, customs department officials, judges, journalists, legislators and so on to create awareness about Intellectual Property Rights throughout the State of Andhra Pradesh.

* * * * *

Andhra Pradesh has a unique signature and head-start over other States of India, in that it has proven expertise and commercial successes in classical biotechnology. Examples of this are, hybrid rice whole organism selection breeding, bulk drug manufacture via synthetic and semi-synthetic routes, and in frontier areas such as, new molecules as drugs, recombinant DNA products, expression vector systems for DNA-based protein manufacture, novel DNA-based vaccines and DNA-micro array-based techniques. The confluence of IT with BT to generate new knowledge and application have started happening at Andhra Pradesh. This Biotech Policy intends to leverage this unique strength and hasten the pace of development of Bio-Technology in the State, so that Andhra Pradesh maintains its status as a premier Bio-Tech State in India.

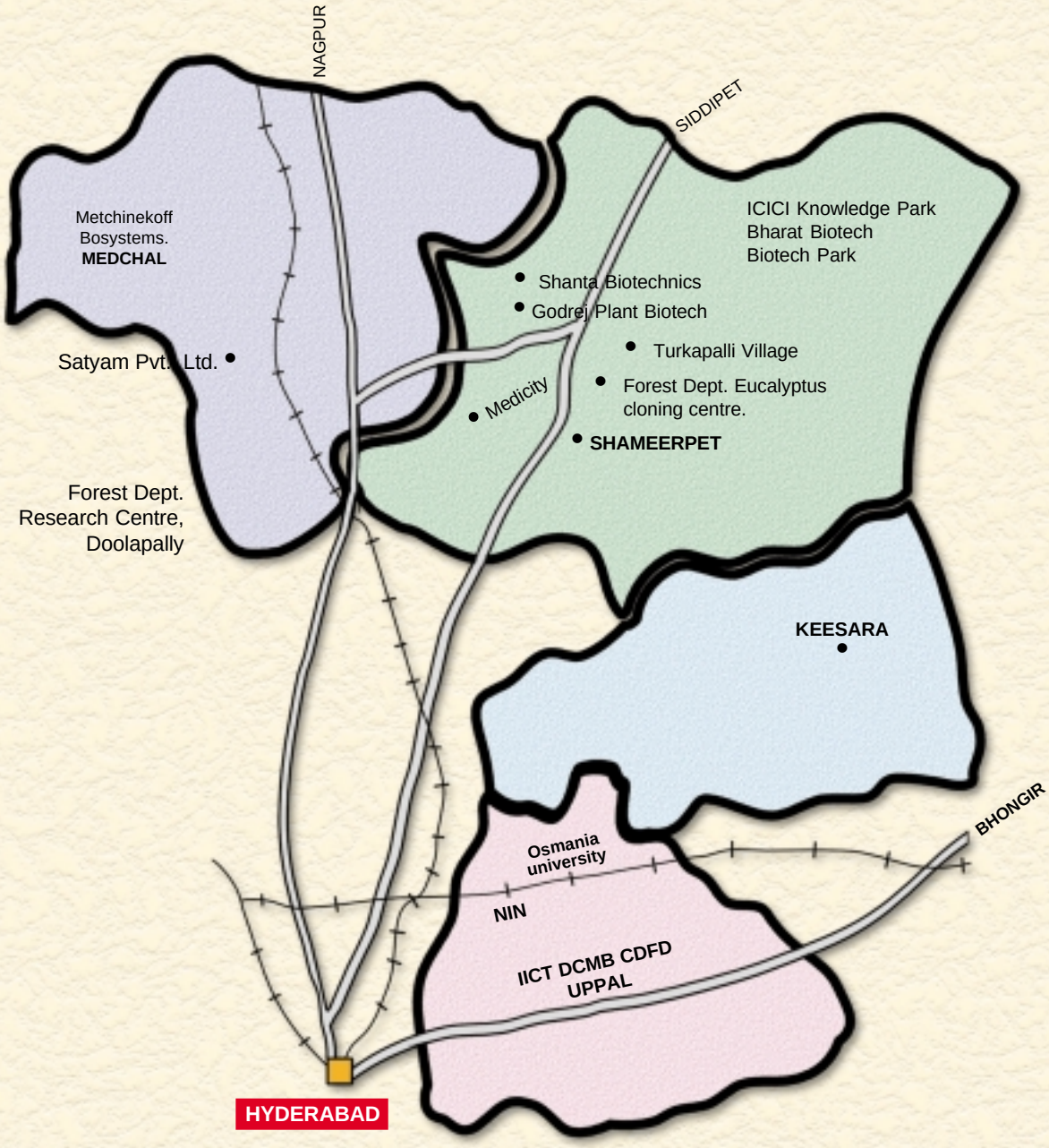
Secretary to Government
Industries & Commerce Department
A-Block (5th Floor), Secretariat, Hyderabad - 500 022.
Tel : +91-40-3450456, 3450508, Fax : +91-40-3450456
E-mail : bp_acharya@rediffmail.com

Commissioner of Industries
Chirag Ali Lane, Abids, Hyderabad - 500 001.
Tel : +91-40-3201235, 3201232-38
Fax : +91-40-3201335, E-mail : comind@ap.nic.in

www.andhrapradesh.com

Touchstone Advtg.

Genome Valley



Shameerpet Mandal	236.50 Sq. Kms.
Keesra Mandal	113.90 Sq. Kms.
Medchal Mandal	188.05 Sq. Kms.
Uppal Mandal	60.90 Sq. Kms.
Total area	**599.35 Sq. Kms.**