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पत्र सूचना कार्यालय
GOVERNMENT OF INDIA
भारत सरकार

The Economic Times, Delhi
Monday, 1st November 2010, Page: 37
Width: 17.82 cms Height: 26.42 cms, Ref: pmin.2010-11-01.31.131

Rising like the Sphinx

THE PHARMA, BIO-TECH, CLINICAL RESEARCH ECO-SYSTEM SHOULD BE REPLICATED IN OTHER SECTORS, TO TAKE ON GLOBAL BRAND NAMES

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India's pharmaceutical industry is the 3rd largest in the world in terms of volume with a total turnover about US$ 21.04 billion, with a domestic market of US$ 12.26 billion which is estimated to touch US$ 20 billion by 2015, making India a lucrative destination for clinical trials for global giants. India tops the world in exporting generic medicines worth US$ 11 billion with a growth rate of 17%. India account for 20% of the global generics market. India is a globally acknowledged source of high quality affordable generic medicine with rich vendor base.

We are poised to become manufacturing hub for pharmaceutical industry of the world and an emerging hub for Contract research, Bio-technology, Clinical trials and Clinical data management. After the establishment of Pharmexil, the exports of our country have grown from around US$ 3.8 billion to US$ 8.9 billion.

AP: Industry Topper

Andhra Pradesh ranks first in the manufacturing of Bulk Drugs and 3rd in manufacturing of formulations in the country. The State is contributing 40% of the total Indian bulk drug production and 50% of the India bulk drug exports.

The state pharma industry and exports are expected to grow at a rate of 20% on par with the country's growth. The sector employs more than a lakh people in the state.

There are over 440 pharmaceutical exporters in the state including major global players like NEKTAR, DuPont and EISAI. The presence of Pharmexil in Hyderabad, and the seed capital assistance to promote pharma exports in the state, has helped immensely. The pharma industry of the state received global recognition in meeting the challenge of H1N1 pandemic.

SEZs

In order to regulate the zoning of the Pharma industry, the State Government has promoted Jawaharalal Nehru Pharma City in an area of 2200 acres at Visakhapatnam with required infrastructure facilities, which is first of its kind in the country.

Similarly, the government has promoted 5 pharma SEZs and 4 biotech SEZs developed by APIIC and local pharma industrialists. A cluster for manufacturing of medical devices and equipments called Medtech Valley has also been launched at Jawaharnagar near Genome Valley, the Biotech Hub of India.

People power

To meet the human resources challenges, the state has promoted 255 Pharma Colleges with an annual in take of 15,240 students and also National Institute of Pharmaceutical Education and Research (NIPER) in association with Government of India to offer post graduate courses and research programs in various Pharma disciplines.

Academy-Industry Bridge

Though there are hundreds of colleges in the state, there is a need to promote quality education in these institutes to enable pharma students acquire the right kind of skills for the pharma sector. The industry has to work closely with the pharma colleges to share the inputs on the industry requirement.

Worldclass Research Institutions

In spite of the above challenges, the state has unique advantage for the development of pharma sector due to the presence of World-class R&D Institutions like CCMB, IICT, ICICI Knowledge Park, CDFD, NIN . That itself should attract investments to the state in this sector.

Policy

An investor friendly industrial policy duly giving a major thrust for pharma and biotechnology sector is a key attraction in the state. The state offers the lowest power tariffs among the industrialized states of the country. The industrial policy covers investment subsidy, reimbursement of VAT, single window clearance system and special incentives for mega projects.

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MINT, Delhi
Wednesday, 10th November 2010, Page: 7
Width: 30.18 cms Height: 12.95 cms, Ref: pmin.2010-11-10.57.10

SAFETY AUDITS

New code for inspecting human drug trials

Guidelines to specify who will conduct inspection, how it will be conducted and the documents required

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NEW DELHI

The drugs regulator has issued guidelines for inspecting human clinical trials for drugs that are being increasingly outsourced to India in an effort to ensure the safety of people who participate in such trials.

The inspection programme will verify if clinical trial investigators and sponsors are complying with the safety guidelines listed in the Drugs and Cosmetics Act, and also sign off on the authenticity of data generated by the trial, said the website of the Central Drugs Standard Control Organisation, or CDSCO.

All trials of drugs, biologic drugs and medical devices will be inspected, it added.

A study by research firm RNCOS Industry Solutions estimates that the clinical trial outsourced market in India will grow at a compound annual growth rate of at least 30% between 2010 and 2012 to around $600 million (₹2,664 crore).

This rapid growth is set to make India one of the preferred destinations for clinical trials—at least in terms of growth. Inspection of trials began in August, when the drugs regulator ordered an audit of a clinical trial conducted at the Bhopal Memorial Hospital and Research Centre (BMHRC) for US-based firm **Theravance Inc. Quintiles Transnational Corp.**, a contract clinical research organisation (CRO), carried out the trial.

> The new guidelines are expected to make inspections the norm rather than the exception

The new guidelines—which specify who will conduct the inspection, how will it be conducted and the documents required from trial sponsors and investigators—are expected to make such inspections the norm rather than the exceptions they currently are.

"Already the CROs have internal audits or engage a third party to conduct audits of the trials they conduct," said D.G. Shah, secretary general of the Indian Pharmaceutical Alliance, an industry lobby group. "Sometimes the trial sponsor gets its own auditor to also check the CRO. All this is already a standard operating procedure for big companies."

Shah added that many companies take corrective measures based on such internal audits of trials as they don't want their image to be tarnished. "However, there is nothing wrong if the regulator wants to do an audit, provided they have trained people conducting the audit, who know what to look for."

Ashesh Shah/Mint

Closer watch: *A file picture of a clinical research centre in Mumbai.*

CDSCO's drug inspectors have been trained by the US Food and Drug Administration. A bigger challenge facing the regulator is that posed by CROs. A parliamentary committee of the ministry of health has asked why CROs have been permitted to conduct trials when they have no legal status in India. They are not mentioned anywhere in the Drugs and Cosmetics Act and there has been no notification to clarify their status either.

"The committee wants to know where they have come from, because CROs are not defined by law in India. So, how are they being given permissions to conduct trials?" said C.M. Gulhati, editor of the medical journal *Monthly Index of Medical Specialities*.

"This is the bigger question because nearly 90% of the trials are being conducted by so-called CROs."