

President of India, Dr. A P J Abdul Kalam's Address

At the inauguration of Wockhardt Biotech Park

September 23, 2004; Aurangabad, India

Biotechnology Research: Challenges

I am delighted to participate in the inauguration of Wockhardt Biotech Park. My greetings to the organizers, pharmaceutical technologists, chemists, doctors, academicians, other participants and distinguished guests. Recombinant biotechnology is indeed a very important route in realizing the biopharmaceuticals. I am happy to know Wockhardt has specialized in this area through research and also has developed and producing many drugs of importance.

The three products: Biovac-B, Wepox and Wosulin produced and marketed by Wockhardt are indeed competitive in the pharma market. I am sure that Wockhardt will keep pace with biotechnology research and also participate in the convergence of biotechnology, information technology and nanotechnologies.

Convergence of technologies

Now we have seen the biotechnology wave following the IT wave that we have experienced earlier. Realizing the importance of this, many institutions in India have built biotechnology parks. We are also seeing a large number of startup companies – much the same way that we had seen during the IT revolution. In a decade from now, the biotechnology would form a very significant part of our economy both domestic and export economy. We have already started seeing the convergence of biotechnology and Nanotechnology as well as biotechnology and information technology.

Now we believe Nanotechnology is the new technology that is knocking at our doors. It has wider applications compared to information technology. It will be the central focus for many technologies to converge and open a large number of applications. Further, this technology will have a large domestic market potential leading to a robust economy. Nano-bio medical sensors will play a major role in glucose detection and endoscopic implants. Drug delivery system will revolutionize the health-care to a large extent.

Innovation in healthcare

Recently I met Prof. Vijay K Varadan of Pennsylvania State University, US. He shared his experience on the possible line of treatment for Parkinson's disease and Epilepsy. The primary symptoms in Parkinson Disease as you all aware are tremor or trembling in hands, arms, legs, jaw, and face, rigidity or stiffness of the limbs, slowness of movement and impaired balance. Prof. Varadan has devised a wireless system for monitoring and control of Parkinson disease. The system consists of an implantable DNA insert in the head region for generating a pulse to the nerve system; controlled either by a modified pacemaker or smart hat. Passive polymer based gyro sensor, are implanted in the tremor location, the sensor gets the power from the Pacemaker and the Pacemaker then reads the tremor motion. The Pacemaker then generates the pulse in the implanted device in the head to control the tremor. This appears to be a promising line of treatment for such diseases. Prof. Varadan also has reported that few patients affected by Parkinson diseases had a full recovery. This is the promising area of research in which many of our Indian pharmaceutical can concentrate.

Competitiveness in drug development

In India many R&D organization and pharma industries discovers the molecules, most of the pharmaceutical molecules are sold to multinationals abroad. The benefit of value addition goes to the foreign companies. The pharmaceutical business in the WTO environment will have to be competitive. Competitiveness springs from the technological strength. The research and drug design, development and acceptance for introduction are indeed a big mission. Particularly Pharmaceutical manufacturers need to prepare themselves for the challenges - design to drug development, production and marketing. I am happy to see, similar work is being done in this biotechnology park.

Intellectual Property Rights

We are now fast moving into the world of Intellectual Property Rights and Patents under the new international regimes which are unfolding before us. To make sure that we do not lose out to any of the IPR issues, it will be necessary to properly document all our research work and to put in our claims for patents whenever we feel it worthwhile to do so. Wockhardt scientists in collaboration with NIPER, certain CSIR Labs and other institutions should become the repository of IPR related activities not only to ensure that we protect our Intellectual Property of the modern times, but also to ensure that our repository of traditional medicinal knowledge is properly documented and can be put to strategic use to prevent IPR piracy.

Present core competence of Pharma industry

Indian Pharmaceutical Industry worth \$ US 4 billion retail sales in domestic market, in addition to US \$ 2.6 billion in exports. Export growth is due to export of new molecules (Generic), especially to regulated markets. Through molecule exports we are only helping the developed countries for value addition. As reported in SCRIP WORLD PHARMACEUTICAL NEWS UK, India ranks 4th in the world accounting for 8% of world's drug production by volume and 1.5% by value. It ranks 17th in terms of export value of bulk actives and dosage forms. Indian exports are sent to more than 200 countries around the globe including highly regulated markets of US, Europe, Japan and Australia. The larger Pharma units number around 200 in addition to 8,000 Small & Medium Enterprises (SMEs) during 2003-04, value of bulk drugs (Rest. 70 billion) and dosage forms produced (Rs. 275 billion) has grown by 15%.

With the adequate infrastructure and production setup, the prices of Indian medicines should be competitive in the world market. A number of buyers from developed markets from North America, Europe regularly source APIs (Active Pharmaceutical Intermediates) and drug intermediates from India. Many Indian companies maintain highest standards in international 'SHE' requirements namely Safety, Health and Environmental Protection in production.

Due to the Government policy initiatives for strengthening research and development in Pharma sector by way of fiscal incentives and other steps to strengthen regulatory mechanism, new R&D set ups with infrastructure are coming up in various regions of the country. Compared to the reported average R&D spending of 2% of turnover in the sector, a few leading Indian Pharma companies have increased their R&D spending to over 5% of their turnover, which is a noteworthy achievement. Results of the R&D, manufacturing of drugs with high quality cost effectiveness and availability world over and higher market penetration should enable India to become the first in production from the present fourth place in the world.

Research and Development

A study by the Confederation of Indian Industry (CII) states that India has an opportunity of launching new drugs developed by the Indian Scientists. Such a drug could be developed at a cost of only \$100 million, one tenth the international norm, because of the high intellectual capital of Indian Scientist coupled with low cost of production. Also India's huge population and the prevalence of a wide spectrum of disease conditions offer a wide patients' resource for clinical trials. The clinical trial cost in India could be as low as \$25 million compared to \$300 to 350 million in the US.

The investigational new drug stage in India is one-tenth the level in America. The negative factors are that the Indian companies will have to face growing competitive pressures from the local operation of western multinationals. Some of these companies would develop tactics such as authorized generics to limit the growth potential of Indian companies. There is also a fear of patent challenges. If our Industry can cope with these problems I am sure the Pharma Industry can definitely be a great wealth generator for the nation.

Conclusion

Whether India has to eradicate leprosy or TB, to prevent spread of HIV by developing anti HIV vaccine, or to control cardio vascular diseases by multiple technologies and practices, we in India need something important apart from resources. That is creative leadership in all fields, particularly in medical field. Who are the creative leaders? What are the qualities of a creative leader? The creative leadership is exercising the task to change the traditional role from commander to coach, from manager to mentor, from director to delegator and from one who demands respect to one who facilitates self-respect. The higher the proportion of creative leaders in the medical field, the higher the potential for successes in medical field in diagnosis, treatment and research for discovering new avenues in healthcare.

I inaugurate the Wockhardt Biotechnology Park and wish all success in your mission of producing and marketing cost-effective quality drugs in the national and international market.

May God bless you.