

## Dr Bhan moots Indo-US innovation forum to spur growth in biotech

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A clarion call to expedite work on building appropriate infrastructural facilities -streamlined, efficient importation processes for bio-pharmaceutical products, dedicated port facilities with cold storage capability, specialized testing facilities and clear and transparent processes was given at the Biotechnology session of the High Technology Cooperation Group (HTCG) meeting held in Delhi.

Dr MK Bhan, secretary, DBT, said, "We are at the beginning of the biotechnology development process. It is critical to create a balance between basic science and translational science, for which the government is ready to invest in research and development." He informed the audience that the biotechnology strategy is ready to go to the Cabinet soon. Lauding the efforts of the US in the field of innovation, Dr Bhan said that due to strong institutional mechanism and structures, the US has been able to keep ahead in the field of biotechnology. He urged the business delegates from the US to increasingly share their experiences and give technical support. He further suggested that the US can be an incredible partner to India as 70 percent of the biotech material is possessed by them. He stressed that there is a need to form a micro group if one is seriously looking at deliverables through trade in biotech between the US and India. He also proposed that there is a need to create an Indo-US innovation forum to spur growth in the sector.

Dr Bhan also pointed out the need to have a point person to coordinate the efforts of the HTCG in a manner which enhances the overall accountability of concerned people in India and the US.

Nigel Thompson, executive director, Economic and Development Strategy, Merck highlighted how important it was to incentivize the innovation process in order to unlock the potential for entrepreneurship and innovation in life sciences. He pointed out that India must address and clarify the issues of scope of patentability and compulsory licensing. Data protection needs to be implemented in accordance with international norms. He added that the complex challenge lies in the issues of investment in innovation, bringing healthcare to people who need it. For this, there is the need to have a broad dialogue and consider processes involving key stakeholders. Echoing Dr Bhan's sentiments, he suggested that there is an urgent need to set up a committee which would work on the details in a focused manner.

Dr Rama Mukherjee, president (R&D), Dabur Research Foundation highlighted three areas where India can contribute. She said India has the potential to come up with solutions in the area of cancer, malaria and avian influenza (bird flu). She pointed out that Dabur's focus is on developing cancer vaccine, redevelopment of anti-cancer drugs using nanoparticle/nanocell technology. She added, "In another two-three years we hope to have few clinical trials." She urged the US companies to join hands to control influenza pandemic and versions of mutated virus by developing therapeutic vaccines.

Dinesh Dua, co-chair, FICCI Biotechnology committee and president, Wockhardt Ltd, stressed that it is critical to move towards synergistic model with India and create national strategies to fight diseases like cancer, malaria and influenza. There is urgent need to expedite synergy between the US and Indian companies particularly in pharmacology and biotechnology, Dua added.

### **Govt to set up IPR management institute with WIPO aid**

The government has proposed the establishment of a National Institute of Intellectual Property Management to address the issues of training, research and policy formulation, to facilitate a fair, equitable and world-class system of patenting in India.

Speaking after inaugurating a two-day national seminar on "Enhancing Global Competitiveness of Indian Life Sciences Industry through the Strategic Use of the Patent System", organized by WIPO, DIPP and FICCI, Dr Ajay Dua, secretary, department of industrial policy and promotion (DIPP), said, "We are in serious discussion with WIPO to create an IP management institute that imparts the requisite skills to IP managers for the corporate sector, attorneys and lawyers, addresses sponsored research work in the IP field and builds up a policy think tank for handling IP issues." Such an institute, combining all the three aspects in IP management, would be the first of its kind in the world, he said.

Dr Dua said, "the scope and management of IP would need to evolve along with the research and patenting requirements of biotechnology, pharmaceuticals and drugs, even as "it has become imperative to bring our traditional knowledge in the public domain so that due credit is accorded to the communities and people who have contributed to creating a body of scientific knowledge."

Jay Erstling, director, Office of the Patenting Cooperation Treaty (PCT), WIPO, said the PCT, of which India is a signatory and a valuable partner, provides simple, cost-effective and time-saving solutions based on best practices to member-countries as inventions get commercialized and disputes in IP arise. In this context, he emphasized the need for settling commercial disputes amicably through the alternative dispute management system developed by WIPO.

### **DST secretary outlines four-point agenda for Indo-US nanotechnology projects**

Prof. VS Ramamurthy, secretary, department of science and technology (DST) outlined a four-fold prescription to the High Technology Cooperation Group (HTCG) to give an impetus towards initiating Indo-US nanotechnology projects.

Addressing the HTCG Dialogue on nanotechnology, Prof. Ramamurthy called for setting up an Indo-US center on computational material sciences with special reference to nanotechnology, the US help in the establishment of a nanotechnology center in India, facilitation of the US nanotechnology enterprises to use ACRI, Hyderabad facilities, including incubator space and creation of a bi-national small business incubator fund.

He outlined India's priority requirements in the field of nanotechnology as investment, trained human resources, innovation and research and interface between industry and research institutions through public-private partnerships.

Mike Roco, senior advisor for nanotechnology, National Science Foundation, USA said the National Nanotechnology Initiative (NNI), a federal R&D program was established to coordinate the multi-agency efforts in nanoscale science, engineering, and technology.

The goals of the NNI are to maintain a world-class R&D program aimed at realizing the full potential of nanotechnology;

facilitate transfer of new technologies into products for economic growth, jobs, and other public benefit; develop educational resources, a skilled workforce, the supporting infrastructure and tools to advance nanotechnology; and, support responsible development of nanotechnology.

### **Area of concern is IPR, says knowledge industry**

Intellectual Property Rights (IPR) remain an area of concern for the knowledge-based industry, felt participants at a session on "From Brains to Business: Future Knowledge-Based Industries" during the India Economic Summit 2005, jointly organized by World Economic Forum and Confederation of Indian Industry.

While India has enacted laws to safeguard IPR, their implementation remains poor. The government and consulting organizations can give advice on patent registration, especially in cultures where copying is rife, said Michael A Cooke, president, SAS International, Germany.

He said India's international capabilities in marketing and branding need to be better projected to attract foreign direct investment (FDI). India should apply know-how and skills from IT to bio-informatics to engineering in order become a lead player. IT has attracted the best Indian engineers and adopted intellectual property rights (IPR), transparency and governance norms, as appropriate.

The IT sector had developed best practices on IPR and patents, and other sectors such as biotechnology could learn from it, said Venkatesh Valluri, president and country general manager, Agilent Technologies, India. In addition, the IT industry could offer valuable insights on how to attract bright Indians settled abroad. Further, the biotechnology industry also needs to make use of the government infrastructure, most of which is under-utilized and collaborate with educational institutes to build a talent pool that will deepen research by funding common themes.

S Mahalingam, CFO, Tata Consultancy Services, India, said IP protection was essential to attract suitable human resources. The biotechnology industry requires doctoral-level professionals in order to grow. It also needs to address wage differentials between India and the West. "It should create centers of excellence," he said. The IT industry, he said, had grown without a domestic market but biotechnology can grow on the strength of the domestic market. For this, the government has to enforce existing laws and institute labour reforms.

### **SRL Ranbaxy launches national mass screening program to wage a war against Hepatitis B**

SRL Ranbaxy, a leading pathology laboratory service provider, has launched a first-of-its-kind national mass-screening project for Hepatitis B amongst school students. Teaming up with Lions Club International, the project, in its first phase, aims to screen and diagnose over 1 lakh school students in Chennai against the deadly Hepatitis B virus.

The program was initiated at Shrimati Ramkumar Devi Fomra Vivekanand Vidyalaya, Crompton, wherein SV Shekhar, Chennai's popular stage performer and a social worker, motivated more than 1500 students, from classes VI to VIII for the Hepatitis B screening by SRL Ranbaxy experts.

Bringing to light some alarming facts on Hepatitis B prevalence, VS Venkatesh, director, sales and marketing, SRL Ranbaxy said, "Out of an estimated 43 million Hepatitis B infected Indian population, nearly 90 percent are 'unaware carriers' and they do not even know that they carry the infection and can spread it further. Furthermore, the prevalence of Hepatitis B is highest amongst the younger age group. Estimates also suggest that 5 percent of the infants carry a probability of picking up the infection from their mothers. These facts clearly establish the criticality of timely and accurate diagnostics - and that too amongst the younger audience if we have to nip this disease in its bud. SRL Ranbaxy decided to employ its expertise to this cause and team up with Lions Club to diagnose school students and create awareness amongst them as well as their families. Whatever the numbers of families that this initiative brings life and new hope to, we would have achieved our objectives."

As part of the campaign, SRL Ranbaxy will employ its specialists and global level quality protocols for accuracy testing. The test reports would be delivered to the students the next day with further counseling, if needed.

Speaking on the occasion, K Bhaskar, governor, Lions Club International said, "Lions Club Chennai has always stood by its citizens, bringing in relevant experts and joining them in several social issues. The estimated prevalence of Hepatitis B in Chennai is an alarming level of more than 6 percent of entire population and if corrective diagnostic action is not taken right now, it could turn out to be an uncontrollable epidemic. It was at this juncture that SRL Ranbaxy approached us and given the fact that they have a national network and international quality systems, we were honored to team with them in this critical project." Post successful implementation in Chennai, SRL Ranbaxy and Lions Club would analyse the feasibility of extending this campaign to other states and carry this revolution against Hepatitis B to all shores of the nation.

### **Shasun Chemicals to conduct clinical trials with r-Streptokinase**

The Genetic Engineering Approval Committee (GEAC) has given permission to Chennai-based Shasun Chemicals & Drugs Ltd to conduct clinical trials with ('Streptokinase â€™A') developed by it in India.

Shasun Chemicals has proposed that it will conduct a multi-center, prospective, randomized, parallel design, double blind study to evaluate the efficacy and safety of Streptokinase â€™A in the treatment of acute ST elevation of myocardial infarction at five centers - Chennai, Madurai, Bangalore (two centers) and Pune. The total number of patients to be tested is about 120.

The GEAC further noted that pre-clinical animal toxicity studies have been examined by the Review Committee on Genetic Manipulation (RCGM) wherein the committee noted that the product is found to be safe. The committee further noted that the product r-Streptokinase is a drug approved for marketing in India.

After detailed deliberations and taking into consideration the recommendation of RCGM and the expert members, the committee approved the conduct of clinical trials with ('Streptokinase â€™A') developed by Shasun Chemicals in India.

### **Mashelkar unveils four-fold strategy to create strong national innovation system**

Dr RA Mashelkar, secretary, Department of Scientific and Industrial Research (DSIR), called for a four-pronged strategy to create a strong national innovation system by leveraging India's human talent, building the capacity and competence of public research institutions, employing traditional knowledge to create Intellectual Property and developing a hassle-free environment to enable companies to take competition head on. Inaugurating the 19th National Conference on "In-House R&D in Industry: Managing Technology for Competitive Advantage - Emerging Indian Challenge," organised jointly by DSIR and FICCI, Dr. Mashelkar said, "We need to worry about the fact that India does not figure in the top 10 emerging nations in terms of R&D investment by business. It is imperative that as enterprises develop their own capacities, the government chips in through enabling policy and investments and forges public-private partnerships to enable India join the big league and be counted.

Dr Mashelkar and the FICCI president, Onkar S Kanwar gave away the DSIR National R&D Awards for 2005 to 11 companies in nine categories. These include: Gujsynth, Vapi and IPCL, Vadodara, (chemical and allied Industries); Matrix Laboratories Ltd, Secunderabad (drugs and pharmaceutical industries); Sri Biotech, Hyderabad (biotech industries); Transasia Bio-Medicals Ltd, Mumbai (electronic/opto electronic industries); Maharashtra State Seeds Corporation Ltd, Akola (agro food processing industries); SAIL (new materials); Praj Industries Ltd, Pune (technology exports); Reliance Industries Ltd, Hazira (technology absorption) and BEL, Bangalore and Rasi Seeds (P) Ltd, Attur ( successful commercialisation of technology acquired from others). Dr Mashelkar said, the emerging role of knowledge in the new economy "gives us the confidence that India would occupy a position of leadership" as currently 50 per cent of GDP of advanced countries comes from the knowledge sector.

### **Clinical research will be built into medical school system: Dr Bhan**

The Indian Council of Medical Research (ICMR) and the ministry of science and technology have taken on hand a massive program of transforming the medical school research system, under which, in the next five years, clinical research will become part of the curriculum of medical schools. This would go a long way in producing skilled, motivated and ethical professionals in the vital area of biotechnology research. This was stated by Dr MK Bhan, secretary, DBT, while addressing the inaugural session of the three-day Bio-Business Summit 2005 â€™ "Global Clinical Trials in India: Challenges and Opportunities", organised recently by FICCI, Department of Biotechnology, Ministry of Health & Family Welfare and ICMR.

Dr Bhan said it was imperative to put in place human resources creation strategies for clinical research in India along with a proper assessment of the optimal training needs for personnel engaged in such research. "Unfortunately, the industry is still

not able to pinpoint the changes that need to be brought about in this crucial area", and therefore it was necessary to create a permanent think tank comprising the best brains of India to prepare documentation for the Drug Controller General of India (DCGI) for assisting the directorate in creating a facilitatory environment for research and drug discovery in the country, Dr Bhan said.

The minister of state for health and family Welfare, Panabaka Lakshmi pointed out that good clinical practices as well as ethics to be followed while conducting clinical trials have to be a shared responsibility of sponsors, clinical investigators, ethics committees and the regulatory bodies. "As our share in global clinical research increases, the challenges would have to be met along with the opportunities thrown up by this intellectual activity. The need of the hour is to identify the deficiencies and prepare for the challenges much in advance and to address them in a speedy and effective manner," the minister pointed out.

### **Critical bill on lines of Bayh-Dole Act likely in Budget session in 2006: Sibal**

Kapil Sibal, minister for science and technology, has acknowledged the need to revolutionise the R&D scenario in India by emulating the Bayh-Dole Act, 1980 of the US. He was addressing the two-day global summit on India R&D 2005, organised by FICCI.

The Patent and Trademark Law Amendments Act more commonly known as the Bayh-Dole Act addresses the critical issue of technology transfer of research results from the universities to the commercial market place for public benefit. With the passage of the Bayh-Dole Act, colleges and universities immediately began to develop and strengthen the internal expertise needed to effectively engage in the patenting and licensing of inventions. This Act provided the strong incentive for university-industry research collaborations. The minister outlined his vision towards creating a similar incentivized atmosphere in India between universities and the industry and said that all efforts will be made to put in place a bill on the lines of the Bayh-Dole Act in the Budget Session in early 2006.

It is notable that before the passage of the Bayh-Dole Act, fewer than 250 patents were issued to the US universities each year. Sixteen years later in 1996, universities received more than 2,000 new patents, executed nearly 2200 licensing agreements, and received royalty income from licensing of \$242 million. Since 1980 more than 1500 start-up companies have been formed based on technologies discovered at academic institutions.

In India, a similar Act is likely to boost R&D efforts and promote technology transfer by creating incentives for university researchers to consider the practical applications of their discoveries, and for universities to search out potential companies to develop them. It is expected that an Act on the lines of the Bayh-Dole will enable corporations to negotiate exclusive licenses of promising technologies.

### **Serum Institute launches Td-Vac for adults and adolescents**

Serum Institute of India Ltd, India's largest vaccine manufacturer, has launched Td-Vac, India's first indigenous Tetanus and Diphtheria vaccine for combating the fatal Tetanus and Diphtheria (Td) in adolescents and adults. Td-Vac is priced at Rs 7.50. It provides safety against Diphtheria and Tetanus (Td), while the Tetanus (TT) vaccine is priced at Rs 6.50. With this vaccine the patient receives protection against two diseases at the cost of just one.

According to an official press release, the Td vaccine is different from the normal DT (dual antigen) vaccine used in children. This new Td vaccine will replace the existing usage of TT (Tetanus) vaccine, which is normally given post-injury. Every person traveling to the US has to prove that he has received Td vaccine dose. In several countries, including the US, pregnant women are administered with Td (Tetanus and Diphtheria) vaccine instead of the TT (Tetanus) vaccine. The Indian Academy of Paediatrics (IAP) recommends the use of Td vaccine in all individuals over the age of 7 years.

Dr Cyrus S Poonawalla, chairman, Serum Institute of India Ltd. said, "Serum Institute has always looked at launching international standard life saving vaccines in the Indian market. Health authorities in the western countries advise the use of Td (Tetanus and Diphtheria) vaccine instead of the TT (Tetanus) vaccine. Now, with the launch of Td-Vac, we are yet again offering the Indian masses the benefit of two vaccines in one, and which is the norm in developed countries."

### **Shantha Biotechnics to conduct Phase III trials of Pentavalent vaccines**

After the successful launch of its quadravalent vaccine Shantetra, Hyderabad-based Shantha Biotechnics will now conduct Phase III clinical trials of r-DTWPHb-Hib Pentavalent Combination Vaccine. Shantha Biotechnics received the green signal from the Genetic Engineering Approval Committee (GEAC) at its meeting held on November 23, 2005.

Pentavalent Combination Vaccine is for a paediatric use in immunization program. Pentavalent vaccine contains Diphtheria

(D) and Tetanus toxoids (T) and the purified major surface antigen of the hepatitis B virus (HBV), Hib polysaccharide adsorbed on aluminum salts and mixed with inactivated whole cell pertussis (P). Shantha Biotechnics proposes to conduct a multi-centric, randomized, single blind, three arm study to compare the immunogenicity and safety of indigenously developed DTPwHB-HIB (Liq) Pentavalent combination vaccine with Easyfive (Liq) and Tritrantrix + Hberix in about 400 children. The route of administration is intra-muscular injection and duration of the study period per subject will be 12-15 weeks. The Review Committee on Genetic manipulation (RCGM), which has examined the pre-clinical animal toxicity studies, noted that product is found to be safe. Taking into consideration the recommendation of RCGM, GEAC has given permission for Shantha Biotechnics to conduct clinical trials with Pentavalent Combination Vaccine.

### **Concordas to expand**

Concordas, the professional services company serving the life sciences industries, is now looking at expanding its operations and has initiated a recruitment drive for its Indian operations. It offers opportunities to graduates of science, pharma and management and to statisticians and market researchers with a flair for consultancy. Concordas is providing services to clients across Europe, US and India. Recent projects have included the evaluation of market characteristics and dynamics of various therapeutic areas in the US for international clients, a series of commercial due diligence evaluations for European specialty pharmaceutical companies, and outsourced marketing analytics for healthcare marketing companies. Colin Greenstreet, founder and chief executive, Concordas said, "The Indian pharmaceutical R&D scene is an exciting one. Indian companies and R&D activities are rapidly internationalizing."