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ABLE head: We help industry, government, academia to interact

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Association of Biotechnology Led Enterprises (ABLE) is a not-for-profit pan-India forum that was launched in April 2003. It has over 400 members from all across the Indian biotechnology industry, representing all domains like agribiotech, bio-pharma, industrial biotech, bioinformatics, investment banks and venture capital firms, leading research and academic institutes and law firms and equipment suppliers.

Dr P M Murali, president, ABLE and managing director and CEO, Evolva Biotech, shares his views on how the associations is helping Indian life science firms.

What is the total number of members of ABLE? What is the eligibility to become a member?
Dr Murali: ABLE has nearly 400 members currently as on April 19, 2013, belonging to different biotechnology segments. However, the total number of active member is just around the 200 mark.

ABLE offers four categories of membership, including membership by invitation, ordinary membership, associate membership and foreign membership. The Membership by Invitation
category is by invitation only and is reserved for companies or individuals who wish to contribute to ABLE. We currently have three different categories under this, including Patron, Sustaining and Affiliate. In Ordinary Membership, biotech companies that have a registered office in India are eligible to become members. Again under this category we have different slabs, based on company turn over and year of business inception. In Associate Membership, individuals and institutions that have an interest in the Indian Biotechnology industry are eligible, including Indian Government and private bodies, research and academic institutions, ancillary and supporting entities, individual members (indian), NGOs, and supporting companies (banks). In Foreign Membership, individual and companies/corporate can be our member provided they are registered company in their respective countries. And same applies to the individual foreign members as per his or her nationality.

Could you tell us about the major focus areas of the association?
Dr Murali: Our primary focus and objective at ABLE is to catalyses a symbiotic interface between the industry, the government, academic and research institutes both domestic and international to accelerate the pace of growth of the biotechnology sector in India, through partnering with the Government in their biotechnology initiatives to deliver optimal policies and create a positive regulatory environment, encouraging entrepreneurship and investment in the sector, providing a platform for domestic and overseas companies to explore collaboration and partnerships, forging stronger links between academia and industry and showcasing strengths of the Indian biotech sector. Our major focus areas are agriculture, advocacy and regulatory, HR and educational, IP and legal, regenerative medicine, omics, bio-energy, and VC and finance.

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Could you kindly elaborate on the major developments, activities and achievements of ABLE in the last two years?
Dr Murali: ABLE's contribution in advocacy by creating optimal regulatory policy guidelines to strengthen different verticals of biotechnology in India is very significant with policy reports like Dr Mashelkar committee report on recombinant products or Prof Ms Swaminathan task force on application of agricultural biotechnology. We also gave guidelines for the 12th five year plan and recommended the planning commission on various policy frame work. ABLE's flagship event, Biotechnology Entrepreneurs Students Team (BEST), in collaboration with India's department of biotechnology (DBT) has acted as a catalyst for launching six new companies by hard core research Students.

A report by ABLE on 'India biotechnology - The roadmap to the next decade and beyond', captures the emerging global and Indian scenarios in all aspect of biotechnology and recommends several policy interventions which have the potential to catalyze the transformation of the Indian biotechnology sector. Maiden reports by ABLE on 'Making India a global hub for fermentation-based industries', builds strong foundation to take next level growth in making India a global hub for the fermentation industry. Document by ABLE such as 'Draft guidelines for human adult stem cells therapy and products in India', help lay down the development, manufacturing, quality control, non clinical requirements of adult stem cell therapy and products. 'A history of biotechnology in India', a book by ABLE, is another very significant achievement, which captures over three decades' journey of this sunrise industry.

ABLE and ABLE-AG also conduct regular networking events focussing on industry-academia collaboration activities. Some of these events included programmes like GENE POLL, Boots Camp Seminar on IPR, curriculum and skill developments programmes with KBITS and BTFS.

What are the major industry-related policy developments that have taken place in the past year in India? Which policies among these were lobbied for by ABLE and why?
Dr Murali: The Indian government has been proactive and supportive in driving the growth of the biotechnology sector by offering grants and tax incentives, and implementing investment-friendly regulations.
FDI up to 100 percent is permitted through the automatic route for the manufacture of drugs and pharmaceuticals. The government has taken several initiatives to promote the growth of the Indian biotechnology sector.

The Indian government has proposed the setting up of the Biotechnology Regulatory Authority of India. This authority is aimed to be set up as an independent body and legal committee to control the production, research, transport, import, and usage of organisms and products of modern biotechnology. Furthermore, Biotechnology Industry Research Assistance Council has been set up to support innovation and provides infrastructure and services to the Indian biotechnology sector. It will also address sector needs by providing a suitable environment to promote and support high-end innovation.

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Moreover, the Indian government has set up a $2.2 billion venture fund for supporting drug discovery and research infrastructure development projects. This is a crucial step as it increases the funding required for innovative work by the Indian biotech sector. The Indian government passed the Clinical Establishments Bill in the year 2010. This move is aimed at standardizing procedures for various clinical trial-related tasks. The bill aims to make registration of clinical trials, as well as clinical research organisations, mandatory throughout India. The Government of India has undertaken food security plan for sustainable crop production research for international development initiative with the specific aim of increasing global partnerships between India and the UK in the field of biological and biotechnological research.

What is the number of MNCs and domestic companies in the industry? How many new domestic companies have been formed in the last two years?

Dr Murali: According to the latest surveys in 2011-12.Today, there are around 380 domestic small, medium and large biotechnology or life sciences companies. Foreign players are also establishing their presence in the Indian biotech space and they are close to 20 companies. For instance NovoNordisk, Eli Lily, GSK, Sanofi Pasteur India Monsanto, Syngenta Sanofi India (Aventis), Pfizer, Novartis and Astra Zeneca are examples of major established MNC players. Denmark-based global biotech company Novozymes has partnered with Bangalore-based biotech company Sea6 Energy in January 2012 for exploratory research and to jointly develop a process for the production of biofuels from seaweed. Lonza is planning to set up a manufacturing base in India at an investment of $150 million at Hyderabad. India-based Clinigene International and Seattle based Pacific Biomarkers announced a collaborative agreement in January 2012 to address the specialty biomarker and high-end clinical trial laboratory needs.

What is the plan of action of the association for the next two years?

Dr Murali: ABLE considers biotechnology as the "technology of hope" for its promising of food, health and environmental sustainability. It is imperative that India leverages resources through partnership and build regional innovation systems. ABLE's strategy will help develop local talent for a globally competitive workforce. While we recognize private sector as a crucial player, the strategy also visualizes government to play a major catalyzing role in promoting biotechnology. The development strategy is based on a strong innovation promotion framework in which industry, academia, organizations and regulatory authorities will communicate in a seamless continuum.

ABLE has formulated strategic plan to address following issues in very structures way in support with our various focus committees. Some of the key policy recommendations and interventions by ABLE include, human resource development in academia and industry, national task force on education & training, strengthening of teaching and R&D in life sciences and biotechnology in the university system, attracting talent to life science and biotechnology, creating science & technology leaders for the industry (Entrepreneurship Developments), advocacy in infrastructure and manufacturing developments, working with state government in building biotechnology parks & incubators to support start-up companies to encourage more and more entrepreneurs to come forward and build bio economy in India, and building regulatory infrastructure.

ABLE has engaged in drafting guidelines and proposals with its various committees so that research and application in biotechnology is guided by a process of decision-making that safeguards both human health and the environment with adherence to the highest ethical standards. ABLE equally focuses and plans to address sectoral road maps for agriculture and food biotechnology, bio resource (marine, microbial, animal and plant), energy and environment, preventive and therapeutic medical biotechnology, regenerative and genomic medicine and diagnostics for emerging diseases. We will also focus on bio-engineering, nano biotechnology, bio-informatics, clinical biotechnology and research services and intellectual property and patent law.

How much revenue have your member companies generated in the past two years? Who have been the top five performing companies in ABLE?

Dr Murali: From the financial data that is available in the public domain, it can be concluded that for the last two years the total revenue of all ABLE firms combines is around Rs 6450.14 crore and Rs 5608.35 crore for financial year 2011-12 and 2010-11 respectively. The top 5 companies across various segments in ABLE (based on revenue as performance parameter) are Serum Institute of India (revenue - Rs 1708 crore), BIOCON (revenue - Rs 1676.4 crore), Panecea Biotech (revenue - Rs 384.22 crore). Bharat Biotech (revenue - Rs 326.2 crore) and Mahyco (revenue - Rs 314.1 crore).