

The Year that Was

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The year 2008 turned out as an eventful period that brought in a gradual metamorphosis to the life sciences industry. Other than the usual drug discovery collaborations, mergers and acquisitions and launching of new products into the market, 2008 saw a change in perspective, business dynamics and strategies of the entrepreneurs.

India is gradually coming out of its shell of isolation and emerging as a major player in the global life sciences industry. The landmark deal between Ranbaxy and Daiichi Sankyo is considered as one of the major events. By selling the majority stake to Daiichi Sankyo, Ranbaxy, the Indian generics giant paved the way for Indian pharma to enter the innovative drug space. In the purely biotech space, we have seen the active implementation of the National Biotechnology Development Strategy (NBDS) under the aegis of the Department of Biotechnology (DBT).

The World Health Organization's (WHO) ultimatum to the National Regulatory Authority (NRA), on the backdrop of the closure of three public sector vaccine making units because of its appalling Good Manufacturing Practice (GMP) standards, came as a death threat to the vaccine industry. The recent setback has been the global meltdown, which has influenced all segments to an equal extent. According to the Biospectrum-ABLE Survey 2007-2008 the biotechnology industry in India has witnessed a 20 percent dip in its growth. Though experts claim that life sciences is an industry which is 'recession proof' ripple effects can still being felt. A sneak peek into some of the milestone events of 2008...

National Biotechnology Development Strategy

It was implementation time for DBT. The announcement of the NBDS in November 2007 was widely welcomed by the industry, as they believed that it would bring about a radical change in the landscape. Initiatives taken by DBT have led to the

formation of tie-ups between the industry and the government, which were unseen in the past. The end of the year also saw the cabinet clearance of BIPP (Biotech Industry Partnership Programme) with a sum of Rs 350 crore earmarked for the scheme during the 11th Plan thus paving the way for technological development and innovation in biotechnology. As a principle, BIPP would strictly promote high risk, transformational technology/process development. No incremental development will be supported. On a broad basis, it is directed at path-breaking research in futuristic technology that has major economic potential to make Indian industry globally competitive and aims at Intellectual Property (IP) creation with ownerships by Indian industry and where relevant, collaborating scientists.

Rejuvenating Research

Dr M K Bhan, secretary of DBT, Government of India, and Dr Mark Walport, director of the Wellcome Trust have initiated the £80m (Rs 640 crore) scheme, jointly funded by the DBT and the Wellcome Trust over five years, with the aim to strengthen the research base of Indian biomedical science by providing fellowship programs to support researchers ranging from newly-qualified post-docs to senior researchers. Each year, the alliance is expected to award around 40 early career fellowships, 20 intermediate fellowships and 15 senior research fellowships. In addition to the new fellowship schemes, the Wellcome Trust has introduced Strategic Awards totaling £15m (Rs 120 crore) to boost the biomedical research in the country.

Indian Gene Decoded

The largest ever study to understand the genetic diversity of India's one billion population, which was conceptualized by Dr Samir K Brahmachari, the director-general of CSIR and Dr Lalji Singh, who heads the Center for Cellular and Molecular Biology (CCMB), was unveiled. The highlights of the study were published in the April issue of the Journal of Genetics, published by the Bangalore-based Indian Academy of Sciences.

"Our study reveals a high degree of genetic differentiation among Indian ethnic groups and suggests that pooling of endogamous populations without considering ethnolinguistics factors will result in false inferences in association studies," said Dr Samir K Brahmachari, one of India's leading geneticists. The study included 32 large populations of sizes above 10 million people and 23 isolated tribal populations representing the vast ethnic, linguistic and geographical diversity of India.

"India represents a global genetic mosaic in its population. The Indian population forms a continuum of genetic spectrum that not only bridges the Caucasians and Oriental Asians and also includes indigenous populations derived mostly from Austro-Asiatic and Dravidian speaking population," said Kapil Sibbal, minister of science and technology who unveiled the study. The findings of the study will facilitate the clinical trials to test the efficacy of drugs in all major populations in India. The data is expected to help the construction of specific drug response maps to aid policy level decision making for drug dosage interventions and disease risk management for complex as well as infectious diseases.

CROs chant globalization mantra

Contract Research Organizations (CROs) have revamped their business strategies wherein they are looking at strategic alliances and partnerships with pharma companies and smaller organizations to augment their business.

As a part of their business model, Siro Clinpharma is first setting shop in Eastern Europe and other non-traditional countries--all of which provide the same advantages like India. Siro has acquired Omega Mediation Group, a mid-sized European CRO for an undisclosed amount. Joining the club are Jubliant, Veeda Clinical Research and Ahmedabad-based Synchron.

Vaccines Issue

The vaccine industry was hard hit this year with the World Health Organization (WHO) giving an ultimatum of October 2008 to the Indian regulators (in this case the NRA) to revamp the regulatory system to avoid derecognition of the NRA. This has come in the event of three substandard public units being shut down resulting in many applications put on hold. In a country, where only 10 percent of the children are vaccinated, this can snowball into a serious issue. BioSpectrum was the first to bring to light this issue in an industry forum, which saw an assemblage of almost all the stakeholders in the industry.

The latest now on the vaccine front is that vaccine makers are now given a five months breathing space (till March 31, 2009) wherein the DCGI can upgrade the regulator's testing labs.

Emerging R&D centers

The year 2008 has seen a lot of Indian and multi-national companies establishing their R&D centers here, making it clear that India is poised to become the R&D hub of the global life sciences industry. DuPont India, a subsidiary of E I du Pont de Nemours and Company recently opened the first biotech research facility at the DuPont Knowledge Center (DKC) in Hyderabad, spread across 15 acres with an investment of Rs 100 crore.

It's still relatively early in the movement of R&D to India but with a focused and a long-term R&D vision, policy framework and commitment coupled with the incentives, which the Indian government is offering, India can go a long way in becoming the biotech R&D hub of the world.

National Biofuel Policy approved

It was in 2003 that India started its Biofuel mission. Five years later, the Union Cabinet in its meeting held on September 11, 2008 gave its approval for the National Policy on Biofuel prepared by the Ministry of New and Renewable Energy, and also approved the setting up of an empowered National Biofuel Coordination Committee, headed by the Prime Minister of India and a Biofuel Steering Committee headed by cabinet secretary.

Ministry of New and Renewable Energy has been given the responsibility of the National Policy on Biofuels and overall co-ordination by the Prime Minister under the Allocation of Business Rules. A proposal on "National Policy on Biofuels and its Implementation" was prepared after wide scale consultations and inter-ministerial deliberations. Group of ministers (GoMs) under the chairmanship of the Union Minister of Agriculture, Food and Public Distribution, Sharad Pawar, considered the draft policy. After considering the suggestions of the planning commission and other members, the GoMs recommended the National Biofuel Policy to the cabinet.

Mergers and Acquisitions

The year 2008 has witnessed some groundbreaking mergers and acquisitions and the prominent among them is the Ranbaxy-Daiichi Sankyo deal. Industry analysts predict that this could mark the beginning of a new era where second generation entrepreneurs will look at issues on a macro level thus changing the landscape of the pharma industry.

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