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# Approval rate for biologics drop in India

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The biopharma sector, which contributes about 60 percent of the Indian biotechnology industry, has been witnessing a compound annual growth rate (CAGR) of 21.63 percent in the last 10 years. The sector witnessed fall in the growth rate in the recent years as compared to the early part of 2000. This is mainly attributed to drop in number of new products launched and also decline in the prices of biologicals due to price war among the Indian manufacturers and multinationals.

Until September this year, about 10 companies have launched biotech products and products related to biotechnology. Five companies in bioinformatics space, four from diagnostics and one from the biopharma area have announced the launch of their products in 2012. In bioagriculture space, 33 companies got approval from Genetic Engineering Approval Committee (GEAC), the apex body constituted under the Ministry of Environment and Forests for marketing 213 Bt cotton hybrids during May 2012 season.

The biopharma sector, specifically in vaccine space, witnessed launches of a few products in 2012 as compared to previous years. In the last three to four years, the number of product launches have fallen from 10 biologicals in 2009 to eight products in 2010, five in 2011 and to just three as of August 2012, according to the Central Drugs Standard Control Organization (CDSCO). The Drugs Controller General of India (DCGI) has given approval to 11 companies for marketing 26 biologicals excluding therapeutic products since 2009 till August 2012.

Three companies have launched their products in biologicals space, during 2012. Ranbaxy Lab, which has acquired Biovel Life Science, a biotechnology company from Bangalore in 2010 has launched haemophilus influenzae type B (Hib) conjugate lyophilized vaccine and Vi capsular polysaccharide Salmonella typhi (Typhoid) vaccine in March for active immunization against haemophilus influenzae type B infection in children of the age group of six weeks-to-five years and for active immunization against typhoid fever for adults and children older than two years of age respectively. In June, Bharat Biotech International got the approval from DCGI for marketing inactivated Japanese encephalitis vaccine. Even Biological E launched inactivated JE vaccine in September.

**Identifing a possible disease or disorder**

Coming to diagnostics space, the DCGI has till August 2012, has given approval for 76 kits from Indian manufacturers (includes 36 HIV diagnostic kits, 21 HBsAg diagnostic kits used in the detection of hepatitis B virus mutation within "a" determinant and 19 diagnostic kit of hepatitis C virus (HCV) for blood bank use. The number of diagnostics kits allowed by DCGI to import and market in India for a similar disease was higher as compared to the local manufaturers (62 kits for HIV, 55 for HBsAg and 46 for hepatitis C virus (HCV). In all India has about 25 companies involved in manufacturing of diagnostic kits, reagents etc.

During 2012, Bhat Biotech, a diagnostic company from Bangalore has launched a dengue kit. The company noted that the kit is very sensitive and easy to use. This kit can detect both antigen and antibodies. It is fast as it is based on the lateral flow immuno-chromatography-based technology. This test can detect the infection within three days of infection. Besides, the market witnessed a soft launch of SES platform by XCyton Diagnostics from Bangalore. The company observed that the platform allows for simultaneous identification of 26 different pathogens in a single sample in a single test. It detects RNA viruses, DNA viruses, bacteria, parasites and fungi in a single sample of 1 ml of cerebrospinal fluid in a single test. Currently, existing products are uniplex PCRs and immunodiagnostics. If a battery of these tests have to be performed it will cost nearly $818-to-$909 (Rs45000-to-Rs50,000) per patient sample and takes seven-to-10 days to complete. SES on the other hand costs only one third of that for a seven hour process.

Reliance Life Sciences, one-of-the-leading life sciences companies of India from Mumbai having wide interest in biotechnology has launched Reli Stat in August 2012. ReliStat is a thrombin-based hemostatic kit for use in surgeries to control excessive bleeding and post operative oozing. Currently there are no similar products existing in the Indian market. Priced at $140 (Rs7,750) per kit, this hemostatic kit is expected to be used by surgeons in various surgeries including oncology surgeries, neuro surgeries, general surgeries as well as laparoscopic procedures. Thrombin supplied as part of the ReliStat kit is manufactured in-house in the state-of-the-art manufacturing facility in Navi Mumbai.

Acton Biotech developed a novel oral alkylating agent, Temozolomide, commonly used drug for Glioma and which has been found to be effective only in patients who have an inactive methylguanine methyltransferase (MGMT). This allows the doctors to determine if Temozolomide therapy will work on a certain patient and if not then the doctor will recommend something else.

Currently, there are 20 recombinant therapeutics, which are approved for marketing in India by the GEAC. Since 2005, the Review Committee on Genetic Manipulation (RCGM) under GEAC has approved 94 clinical trials to be conducted in India related to recombinant pharmaceutical and therapeutic products recommended by the DCGI. There are close to 100 biopharmaceutical companies actively involved in R&D, manufacturing and marketing of biologics in India. No Indian company has launched recombinant therapeutic product during 2012.

**Software tools and technologies**

To support the R&D, which is taking place in drug discovery, to over coming the failures in selecting the target candidate molecules for clinical trials, many companies with back ground in science, technology and mathematics have been developing tools. Strand Life Sciences, the first company in India to start its operation in bioinformatics space in 2000 in Bangalore has developed many tools and later added additional features to the same for providing value addition to the tools. In 2012, Strand launched Hepatotoxicity Prediction Platform a novel systems approach to model pathways in the liver and combined it with in vitro measurements to create a detailed predictive platform. The platform is capable of providing insight into Drug Induced Liver Injury (DILI). This unprecedented approach will help in replacing or reducing animal usage, and increase efficiency of drug development by predicting hepatotoxicity.

Similarly V Life Sciences from Pune has launched ViTAL (VLife Toxicity Alerts) that can predict the genotoxic potential of a compound based on identification and significance of structural alerts. The product will help the companies to assess the genotoxic potential of new products, especially while entering into regulated markets as regulatory authorities and regulations like EMEA, EDQM, USFDA, REACH etc. provide guidelines on threshold of toxicological concern and safe, acceptable limits of genotoxic impurities associated with the active pharmaceutical ingredient.
BioAxis from Hyderabad has come up a repository of tools, bio-softwares, research protocols and packages which offer a wide range of solution in the multidisciplinary area of life science research. It is equipped with routinely used molecular biology, microbiology, immunological needs and other requirements like DNA, RNA and protein sequence annotation and identification to the fully loaded working environments of microarray data analysis and deep sequencing.

Bangalore based Polyclone Bioservices has introduced ePep, a comprehensive web-based tool developed for designing peptides with chemical modifications and analyzing different properties of peptides. ePep calculates 35 different properties of a peptide which are classified into six broad categories and provides graphical overviews of the results in the same webpage.ePep also enables 69 different chemical modifications that can be incorporated with a user friendly interface.

While some companies are focussing on developing platform, tools, systems, a few others have focussed on building a proper database. Molecular Connections has started offering MCPaIRS (Molecular Connections Patent Information Retrieval System), the first Indian Patent Full Text Database with Legal status. The data is hand-curated by domain experts and provided in an easy to use web interface for use by patent analysts, attorneys and IP departments of the world. MCPaIRS contains full texts of granted patents and published applications, and may customizable.

The bioinformatics tools, diagnostic and biopharma products launched this year, are all set to directly impact the general public since they are focused on India specific issues. An innovative dengue testing kit, a indigenously developed and manufactured Japanese encephalitis, a platform diagnostic for a wide variety of pathogens are just some of the novel solutions for disorders prevalent in this geography.

A large number of these products are developed by small or mid-sized start-ups indicating that they are slowly becoming the centres of innovative translational research in India. Government grants alongwith scientists having domain specific expertise has helped a majority of them break the barrier associated with size of the company.

The Indian companies have the potential to become true global players in biologicals and biosimilars mirroring the strong position it has in small molecule generics. For this to come to fruition India needs a concerted approach to boost both research and development in biopharma and strengthen the wider ecosystem supporting this segment of the industry.