

Biologicals approval on decline

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India needs a concerted approach to boost research and development in biopharma and strengthen the ecosystem supporting the growth of the segment

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The biopharma sector, which contributes about 60 percent of the Indian biotechnology industry, has been witnessing a compounded annual growth rate of 21.63 percent in the last 10 years. The sector witnessed a fall in the growth rate in the recent years. This is mainly attributed to drop in number of new products launched and decline in the prices of biologicals due to price war between the Indian manufacturers and multinationals.

Till September this year, about 10 companies have launched biotech products and products related to biotechnology. Amongst these five companies, are in bioinformatics space, four are in diagnostics and one is 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.

Products launched by Indian biotech companies in 2012

| No. | Product | Sector | Company | Launch date | Price |
|-----|------------------------------------|----------------|------------------------|----------------|---|
| 1 | Hepatotoxicity Prediction Platform | Bioinformatics | Strand Life Sciences | March 2012 | \$12000 per drug to be tested |
| 2 | MCPaIRS (Patent Database) | Bioinformatics | Molecular Connections | January 2012 | \$3000 per license |
| 3 | ViTAL (VLife Toxicity Alerts) | Bioinformatics | VLife Sciences | July 2012 | Not provided |
| 4 | BioAxcell | Bioinformatics | BioAxis | July 2012 | License purchase at  Image not found or type unknown 20,000 |
| 5 | ePep | Bioinformatics | Polyclone Bioservices | January 2012 | ePep integration charges: \$2,000. Annual subscription charges: \$2,000 |
| 6 | act on Temozolomide (MGMT) | Diagnostics | Acton Biotech | January 2012 |  Image not found or type unknown 7500 |
| 7 | Dengue NS1 and IgG + IgM Test Kit, | Diagnostics | Bhat Biotech | August 2012 | 160 per test |
| 8 | SES platform | Diagnostics | XCyton Diagnostics | January 2012 |  Image not found or type unknown 15,000-18,000 per patient sample |
| 9 | Reli Stat | Diagnostics | Reliance Life Sciences | August 2012 |  Image not found or type unknown 7,750 per kit |
| 10 | Inactivated JE vaccine | Biopharma | Biological E | September 2012 |  Image not found or type unknown 985.00 for 0.5ml Vial |

The biopharma sector, specifically the vaccine space, witnessed a launch of fewer products being launched in 2012 as compared to that in previous years. In the last three to four years, the number of product launches has 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 three companies, which have launched their products in biologicals space during 2012 include Ranbaxy Laboratories, Bharat Biotech International, and Biological E. 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 6 weeks to 5 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.

Identifying a possible disease or disorder

Coming to diagnostics space, the DCGI, 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 ϵ 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 manufacturers (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 and reagents.

During 2012, Bhat Biotech, a diagnostic company from Bangalore has launched 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 immunochromatography based technology. This test can detect the infection within three days of infection.

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the-art manufacturing facility in Navi, Mumbai.

Besides that, 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 one 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 45,000-50,000 per patient per sample and takes 7-10 days for completion. SES on the other hand costs only one third of that for a seven hour

Reliance Life Sciences, one of leading life sciences companies of India from Mumbai, having wide interest in biotechnology has launched ReliStat 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 7,750 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-

List of biologicals approved for marketing from 2009 till August 2012

| S.No. | Firm | Molecule Approved | Date |
|-------|--|---|--------------|
| 1 | Biomed, Ghaziabad | Meningococcal polysaccharide vaccine (Group A & C) | Dec 01, 2009 |
| 2 | Serum Institute of India, Pune | Diphtheria, Tetanus, Pertussis, Hepatitis-B and Haemophilus Influenzae Type b Conjugate Vaccine Adsorbed, liquid. | Dec 12, 2009 |
| 3 | Panacea Biotec, New Delhi | Oral Poliomyelitis Vaccine (Type 1, 2, & 3) | Feb 24, 2009 |
| 4 | Shantha Biotech, Hyderabad | Killed Bivalent (O1&O139) oral cholera vaccine | Feb 24, 2009 |
| 5 | Panacea Biotec, New-Delhi | Diphtheria, Tetanus and whole cell pertussis (DTwP) vaccine | Mar 19, 2009 |
| 7 | Biovel Life Science (now part of Ranbaxy Lab), Bangalore | Haemophilus Influenza type b (Hib) conjugate vaccine | Mar 24, 2009 |
| 8 | Biovel Life Science (now part of Ranbaxy Lab), Bangalore | Vi Capsular Polysaccharide Typhoid vaccine | May 24, 2009 |