



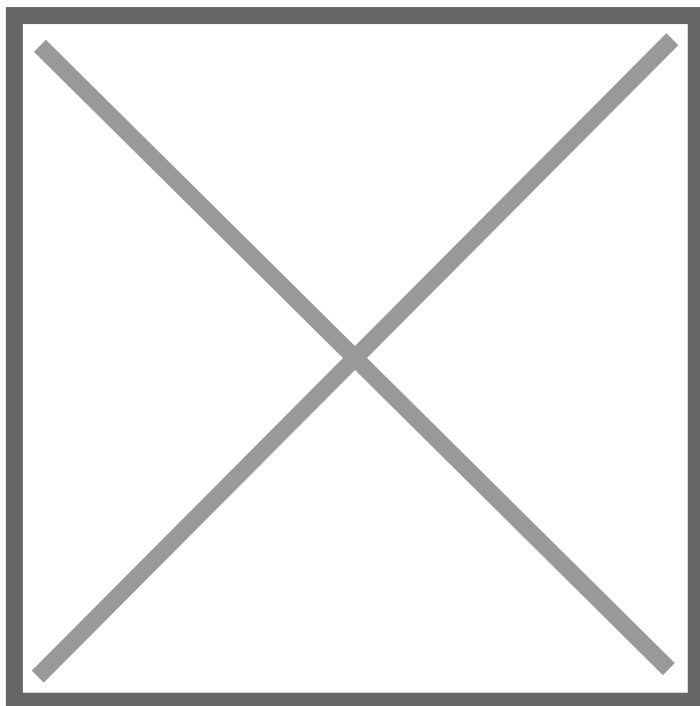
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Biologicals approval on decline

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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

Coverpageimage1

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 ₹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	₹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	₹15,000-₹18,000 per patient sample
9	Reli Stat	Diagnostics	Reliance Life Sciences	August 2012	₹7,750 per kit
10	Inactivated JE vaccine	Biopharma	Biological E	September 2012	₹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 $\Delta C\Delta$ - $\Delta A\Delta$ - Δ 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.

Coverpageimage2 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 immunodiagnosics. 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 process.

Coverpageimage3 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-the-art manufacturing facility in Navi, Mumbai.

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 Biotech, 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 Biotech, 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
9	Biologicals E., Hyderabad	Reconstituted pentavalent vaccine(diphtheria, tetanus, Pertussis (whole cell),Hepatitis b (r DNA) and hib conjugate vaccine (adsorbed)	Sep 23, 2009
10	Panacea Biotech, New Delhi	Bivalent Poilo Ty 1& Type 3 vaccine , Live Oral	Nov 19, 2009
11	Hafkine Bio-Pharma, Mumbai	Bivalent Poilo Ty 1& Type 3 vaccine , Live Oral	Jan 01, 2010
12	Bharat Biotech International, Hyderabad	Bivalent Polio Type 1 & Type 3 vaccine , Live Oral	Mar 12, 2010
13	Cadila Healthcare, Ahmedabad	Influenza Vaccine (Live Attenuated freeze dried) for Intranasal.	Jun 18, 2010
14	Serum Institute of India, Pune	Influenza Vaccine (Live Attenuated freeze dried) for Intranasal.	Jun 18, 2010
15	Panacea Biotech, New Delhi	DTwP-vaccine (adsorbed)	Sep 21, 2010
16	Biologicals E., Hyderabad	Liquid pentavalent vaccine	Sep 29, 2010
17	Bharat Biotech International, Hyderabad	Pandemic Influenza Vaccine A(H1N1) Virus vaccine (Inactivated)	Sep 30, 2010
18	Panacea Biotech, New Delhi	Inactivated H1N1 split virion Influenza vaccine (adjuvanted)	Nov 08, 2010

19	Panacea Biotech, New Delhi	Bivalent Oral Poliomyelitis Vaccine Type 1 and Type 3, Live (Oral)	Apr 29, 2011
20	Serum Institute of India, Pune	Influenza Vaccine (Whole Virion, Inactivated) (Pandemic H1N1 Vaccine), (Embryonated hen eggs derived and inactivated by betapropiolactone	Jun 02, 2011
21	Cadila Healthcare, Ahmedabad	Rabies Vaccine, Human IP (Purified Chick embryo cell culture rabies vaccine) PCECVPM	Aug 16, 2011
22	Biologicals E., Hyderabad	Japanese Encephalitis Inactivated Vaccine	Sep 29, 2011
23	Serum Institute of India, Pune	Meningococcal A Conjugate vaccine, Lyophilized (Clear glass vial with white Aluminium flip-off seals)	Oct 18, 2011
24	Ranbaxy Bangalore	Haemophilus Influenzae Type b (Hib) conjugate lyophilized vaccine	Mar 14, 2012
25	Ranbaxy Bangalore	Vi capsular polysaccharide Salmonella typhi (Typhoid) vaccine	Mar 14, 2012
26	Bharat Biotech International, Hyderabad	Inactivated Japanese Encephalitis Vaccine	Jun 07, 2012

Source: CDSCO

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

DRUG APPROVALS

India has approved 98 drugs in 2011 for the treatment of many diseases ranging from iron deficiency anaemia to treatment of mild to moderate hypertension and for relief of symptoms of allergic rhinitis to treatment of neuropathic pain. This number has dropped to 22 as of August 2012. However, the number of drugs approved was on rise since 2006 with 161 approvals for marketing in India, to 188 drugs in 2007, 270 drugs in 2008. In 2009, the number of drugs that received the approval were 217. The number increased again in 2010 as the DCGI has given approval for 224 drugs

Source: Drug Controllers General of India

Currently there are 20 recombinant therapeutics 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. Though there are several Indian biopharmaceutical companies actively involved in research and development, manufacturing and marketing of biologics, none of these has launched a recombinant therapeutic product during 2012.

Software tools and technologies

To support development activities in drug discovery and to overcome the failures in selecting the target candidate molecules for clinical trials, many companies with background in science, technology and mathematics have been developing smart 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 some of these tools. In 2012, Strand has launched Hepatotoxicity Prediction Platform, a novel system 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.

Coverpageimage4Similarly, VLife 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, and REACH 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 with a repository of tools, biosoftwares, research protocols and packages which offer wide range of solution in multidisciplinary areas 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.

Coverpageimage5While some companies are focussing on developing platform, tools and 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.

Coverpageimage6

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, an indigenously developed and manufactured Japanese encephalitis vaccine, a diagnostic platform 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 have helped a majority of them break the barrier associated with the size of the company.

Indian companies have the potential to become truly 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.

Narayan Kulkarni and Manasi Vaidya (with inputs from Vipul Murarka)