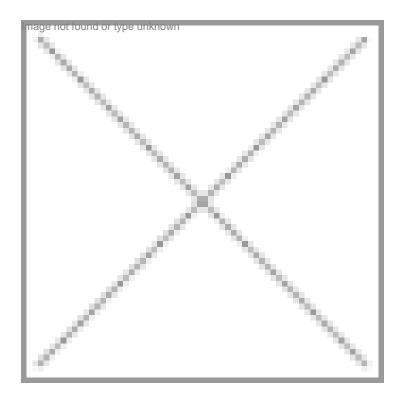


## Anticancer focus on the rise

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Anti-cancer drugs sales recorded \$34.6 billion in sales in 2006 globally with close to 95 products in late-stage trials.

In 2006, at least 31 new drug molecules were launched in the world's key markets. Amongst these, some of the prominent releases were in the area of cancer treatment. These include, Gardasil, the first vaccine to prevent cervical cancer and Sutent for renal cancer. Out of the several drugs that were in Phase III clinical trials or are reaching the pre-approval stage, 95 of them are anti-cancer products.

Anti-cancer drugs recorded \$34.6 billion in sales in 2006. The growth rate was 20.5 percent, which was the highest among the top 10 therapeutic classes. It was fuelled by the demand for innovative anti-cancer therapies. The innovation was at its highest in the oncology segment with over 380 compounds in development.

Nearly half the oncology products in late-stage development are targeted therapies. "Targeted therapies have revolutionized the way cancer is being treated-opening up the possibility that many forms of the disease can be fought through long-term maintenance therapy," said Titus Platter, vice president, IMS Oncology. These therapies are helping to win individual battles against cancer, enabling us to think of it as a chronic illness, rather than a life-ending one. With the industry's innovation and ongoing scientific advances, growth in targeted therapies will continue to be very strong and the outcomes even more impressive, he added.

## **Indian Companies**

With the incidence of cancer cases rising in India, companies have realized the potentialities that this segment has to offer. Bangalore-based Biocon launched BIOMAb EGFR, a therapeutic monoclonal antibody-based drug for treating solid tumors of epithelial origin, such as head and neck cancers, in 2006. The drug is the first of its kind to be clinically developed in India and is the first anti-EGFR humanized monoclonal antibody for cancer to be made available anywhere in the world. This drug is engineered to specifically target and block the epidermal growth factor receptor (EGFR) responsible for the proliferation of cancer cells. "BIOMab EGFR is competitively priced, making cancer treatment more affordable. We aspire to become a key player in this segment," said Biocon chairman and managing director, Kiran Mazumdar-Shaw. The product has shown consistent response in clinical trials initiated both in India and globally and is produced at its manufacturing facility in India.

In January 2007, Dabur Pharma launched Nanoxel, a new version of an existing anti-cancer drug Paclitaxel, which is a nanoparticle-based formulation. The new drug can be delivered in higher doses while reducing side effects associated with chemotherapy. The generic anti-cancer drug Paclitaxel is not usually soluble in water or blood, and so must be administered to patients in a castor oil-based solvent called cremophor that itself can cause dangerous side effects. Dabur has a strong focus on developing cancer vaccine, redevelopment of anti-cancer drugs using nanoparticle/nanocell technology, etc.

Panacea Biotec forayed into the oncology segment in June 2007 to provide treatment for breast cancer, brain tumor, ovarian cancer, pancreatic cancer, prostrate cancer and colorectal cancer. For this purpose Oncotrust was established as the new Strategic Business Unit (SBU) of Panacea Biotec with 50 sales specialists. The company aims to garner Rs 15-20 crore in sales from the oncology chemotherapy segment in the next three years. It launched five cancer drugs namely Paclitrust, Docetrust, Gemtrust, Zoletrust, and Temotrust in 2007. It is also expected to launch some novel drug delivery based anticancer drug in next 2-3 years. "We plan to develop novel and innovative drug delivery systems (NDDS) of the existing anticancer molecule. The new research based drug development will take 2-3 years as we need to develop an effective distribution chain and occupy a significant market share in oncology drugs," said Rajesh Jain, joint managing director, Panacea Biotec.

Dr Reddy's Laboratories Ltd in May 2007 launched Redituxa, its brand of rituximab, a monoclonal antibody (MAb) used in the treatment of Non-Hodgkin's Lymphoma (NHL). The company has also launched a social initiative, Sparsh, an assistance program for cancer patients undergoing treatment. The needy patients identified by the doctors through Sparsh would be provided Redituxa free of cost.

In an effort to strengthen its oncology business, the Hyderabad-based Dr Reddy's Laboratories has launched its fourth anti-cancer product, named Cantop, a lyophilized form of topotecan hydrochloride. Dr Reddy's currently markets three anti-cancer products -Mitotax (paclitaxel), Dacotin (oxaliplatin), and Docetere (docetaxel). Mitotax is indicated for ovarian and breast cancer after the failure of first line therapy. Dacotin is for colorectal cancer, while Docetere is for lung and breast cancer.

Pune-based Serum Institute of India signed a licensing agreement with London-based Lipoxen Technologies in 2005, for a major product development program. The agreement involved eight new product candidates, including protein drugs such as GCSF and EPO, anti-cancer drugs and vaccines. Serum Institute of India would provide the active ingredients and Lipoxen enhanced delivery systems. The agreement combines Lipoxen's strengths in intellectual property and innovation in the drug delivery field. In fact, Serum Institute has started focusing on anti-cancer drugs many of which have gone off patent in the US and Europe.

In September 2007, Ranbaxy Laboratories Ltd signed an exclusive in-licensing agreement with Sirtex Medical Pvt Ltd (Sirtex), Australia, to promote and market Sirtex's product, SIR-Spheres. The product, approved by the US Food and Drug Authority, is used for the treatment of patients with inoperable tumors from primary colorectal cancer that have spread to the liver (Unresectable Metastatic Liver Tumors from Primary Colorectal Cancer). SIR-Spheres have been used to treat many hundreds of patients with liver cancer in Australia, New Zealand, Asia, Europe and the US in a variety of clinical trials and general practice.

In October 2007, Ranbaxy Laboratories and Zenotech Laboratories Ltd announced the signing of definitive agreement, where by Ranbaxy increased its equity stake to 45 percent from 7 percent. Zenotech has received approvals for sale of three of its products in the oncology and biopharmaceuticals areas. These include GCSF (Granulocyte Colony Stimulating Factor), GMCSF (Granulocyte Macrophage Colony Stimulating Factor) and IL-2 (Interleukin-2). For the latter two, Zenotech is the first to receive approvals in India, and has a pipeline of further seven biopharmaceutical products in different stages, all developed inhouse. It has state-of-the-art manufacturing facilities in Hyderabad, and its R&D facilities are in Hyderabad and New Jersey, USA.

Looking the potential of this market, Manipal Acunova, promoted by the Manipal Group, is investing \$10 million to position itself as a biotech and clinical research company. In the clinical research space, the company has tie ups with Biocon India, Pfizer, and AstraZeneca for cancer drug trials. As a contract research organization, Manipal Acunova will focus on drug discovery work for the bio-pharma companies using basic biology and chemistry route. Cancer and diabetes are its focused areas.

## Other players

Roche Scientific Company in April 2006 launched its anti-cancer drug Tarceva (erlotinib), which prolongs and improves quality of life of patients, suffering from lung cancer. Tarceva is a novel therapy for patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) after failure of at least one prior chemotherapy regiment.

It is an oral tablet taken once a day and had the potential to treat many types of solid tumors

In Sep 2006, Merck Specialities, the Indian subsidiary of Merck KGaA, has announced the introduction of ERBITUX, a new gold standard targeted therapy for the treatment of Colorectal Cancer (CRC) in India. ERBITUX works by targeting the Epidermal Growth Factor Receptor (EGFR) which is found on the surface of cells and is involved in the stimulation of cellular growth, replication and/or differentiation when stimulated by growth factors. EGFR has been shown to be involved in the development and progression of many common types of cancers.

These are just a few examples of the major happenings in this sector.

-Jahanara Parveen