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In Focus: India preferred as an outsourcing destination

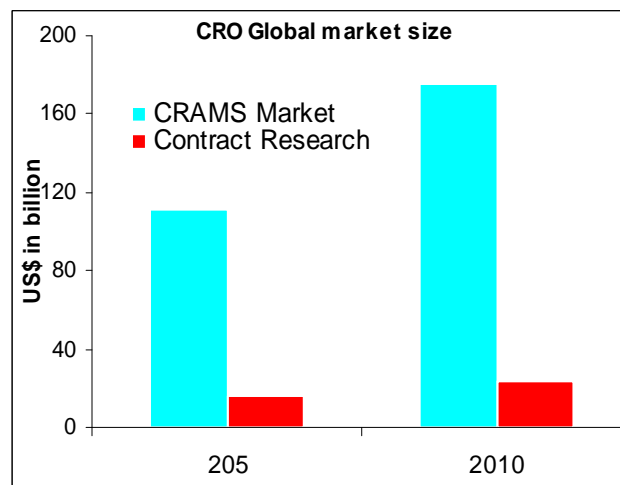
Pharma Companies get tax holiday for clinical trials:

In a Cabinet note on the new drug policy the chemicals and fertilizers ministry, Govt of India has proposed that pharmaceutical companies should be given a 10 year exemption from the 12.24% service tax for Testing experimental drugs on human beings. Currently, the services are provided by hospitals and specialized firms called clinical research organizations (CRO). The government clarified in the Finance Bill that it would include clinical testing of drugs and formulations too.

Present Indian Scenario: Though basic R&D for discovering new candidate drugs are largely carried out in-house by most companies, development and supply of chemical libraries for screening, scaffolds, synthons and reagents used as building blocks for new molecules are subjects for outsourcing. Leading companies outsource projects which are routine, have strict time schedules and are IP sensitive. Syngene and Aurigene in Bangalore, Sanmar Specialities, Shasun Chemicals in Chennai, Ranbaxy in Delhi, AVRA Labs and GVK Bio in Hyderabad and several others including many National Laboratories in India have arrangements with the US and European Companies to carry out specific jobs in a cost and time effective manner

World CR market to touch US\$24 billion in 2010:

World-wide contract manufacturing and research for the pharmaceuticals industry was estimated to be worth US\$11.80 billion in 2005 growing to US\$175 billion by 2010. The largest share of contract manufacture and supply was for Over the Counter (OTC) and nutritional products that is expected to cross US\$100 billion by 2010. Contract research market in 2010, will be worth US\$24 billion up from US\$15.7 billion in 2005. A new development in the area of outsourcing is that the outsourcing activities are progressively moving out of U.S. and Europe to others, notably, China, India, Korea, Russia and Taiwan. Over the years some of the premier companies in the U.S. such as Albany Molecular research Inc, J-Star Research of New Jersey and many others have seen a decline in revenues due to more companies going off-shore primarily due to lower costs. For example, it has



Source: www.pharmabiz.com; Cygnus research

been reported that while the cost to a company of a Ph.D. scientist in a CRO is US\$250,000 in U.S. the corresponding figures in these countries will be much lesser between US\$30,000 to 40,000.

Opportunities for India:

Indian pharma companies have three major opportunities in the global scene. They are:

- Major suppliers of Generic Bulk Drugs and Formulations to the Global markets
- Destination for contract research, custom synthesis, contract production and clinical research.
- Involved in new drug research including discovery of candidate drugs, protecting through patent system and licensing on commercial terms for development by the third parties.

Industry offer:

India has unique strengths in areas of chemical technology to develop innovative processes, custom production of synthetic drugs involving highly sophisticated technologies and clinical research. In all these areas Indian companies can indeed develop strategies for entry into long term contractual arrangements with leading R&D based pharmaceutical companies and develop synergistic collaboration ventures. It is assumed that 30-35% of total drug discovery and development costs are mostly on clinical research. These costs could be reduced considerably when these activities are outsourced from low cost economic countries like India.

Advantage to India:

Apart from lower costs on manpower, there is the availability of large and diverse patient populations, skilled clinicians, ability to meet global International Conference on Harmonization (ICH) guidelines etc for conducting clinical trials with human ethics. English speaking professionals with excellent communication facilities and adequate documentation and analytical systems are the other advantages of India. Varied population with different races, different climatic zones are also the advantages that India has. Over a dozen Clinical Research Organizations have been set up in the country in the last 10 years and many trials have been carried out meeting the FDA standards in India.

Threats:

The real threats come from within the country as well as from outside. Proliferation of CROs with short term goals and little understanding of the intricacies of global regulatory requirements lead to erosion of standards, unhealthy competition, price wars and consequently credibility loss among the international partners. Wherever Chinese industrial units are able to offer products and services, they have invariably undercut India on the price front. Wherever raw materials are to be imported, fluctuations in their prices adversely affect costs of production. When outsourcing is seen as a threat to domestic industry and employment opportunities, countries may opt to bring in legislations to control them as has been done in some states in the US. Non-tariff barriers including imposition of phyto and phyto-sanitary measures and standards on labour and environment could stand in the way of growth of the outsourcing opportunities in India.

Government support:

The Government has committed to supporting outsourcing activities in the Biopharma industry. It is encouraging the industry by providing tax holidays, amendments to suite the present situation like recent changes in Schedule Y of the Drugs & Cosmetics Act, which in turn are attracting many more international players to India for outsourcing clinical trials and research activities.

Outlook

Many drug makers are choosing India as a destination for their outsourcing activities, most of the skilled professionals will get employment directly and many unskilled people would get employment indirectly. It will reduce the unemployment problem to some extent in India. Most of these are multi nationals, foreign exchange reserves will increase. Many poor patients who are not able to get medicine can be treated with these drugs. In the coming years due to an increase in the outsourcing activities, unemployment will decrease and a change in the life style of Indian people will really indicate that "INDIA IS TRULY SHINING"



INTERNATIONAL

AMERICAS

USA: Pharmacopeia partners with Wyeth

Pharmacopeia Drug Discovery Inc. has agreed to partner with drug maker Wyeth on therapies that block a certain protein regulating the body's immune system. According to the agreement, Pharmacopeia will get a US\$5m upfront payment and could receive up to US\$9m in research funding over the next three years for therapies based on the inhibition of the JAK3 protein. Research studies have shown the inhibition of JAK3 shows promise as a treatment for rheumatoid arthritis, psoriasis and certain other immunological disorders. Under the agreement, Pharmacopeia stands to earn up to US\$175m in milestone payments along with double-digit royalties on products resulting from the collaboration.

USA: Eli Lilly will settle some Zyprexa suits

Eli Lilly will settle more liability lawsuits for its anti-psychotic medication Zyprexa for less than US\$500m. The settlement covers more than 18,000 claims that the company did not adequately warn patients taking the medication of a heightened diabetes risk. While the company has settled more than 8,000 similar claims for a little less than US\$700m in the first half of 2005. The company did not disclose the exact amount of the new settlement. According to Tarra Ryker, Eli Lilly, the new settlement covered more plaintiffs for less money as these particular cases were less viable because a 2003 Zyprexa labelling change addressed a possible diabetes risk. Zyprexa sales accounted for 28% of Lilly's US\$3.86 billion in revenue in the most recent quarter Apr-Jun 2006

USA: Novartis tops in Bank of America's drug stock

Bank of America named Swiss drugmaker Novartis its top drug pick for 2007, because of its attractive late-stage pipeline and earnings growth potential. Prudential Equity Group LLC raised its fourth quarter earnings estimates on Novartis to 79% a share, from 74% a share because of higher revenues and lower sales and marketing expenses, following a delay in the launch of two new drugs. The Prudential lowered its earnings estimates for 2007 to US\$3.38 per share from US\$3.49 a share, citing costs that will be associated with several new product introductions over the next 12 months. Prudential analyst Tim Anderson wrote in a report that he expected the company to perform well this year.

USA: Qualicaps will take over Pharmaphil

Qualicaps Group is setting up to complete the acquisition of Ontario-based firm Pharmaphil. Pharmaphil is a manufacturer of empty gelatine capsules, the same line of business as Qualicaps who supply empty two-piece gelatine and non-gelatine capsules and capsule-filling and sealing equipment. Qualicaps has manufacturing sites in Spain, Japan and the US, and under the terms of the agreement Pharmaphil will become a subsidiary of the US-based operations. While the conditions and terms of the acquisition agreement were not disclosed. Qualicaps is expecting a strong market scenario in Injectibles and capsules by this acquisition as Pharmaphil has been in the capsule manufacturing business for over 40 years and has versatile empty capsule products that can be used with powders, pellets, beads, tablets, pastes and liquids.

Europe

UK: Eli Lilly closes its drug manufacturing plant in England

Eli Lilly has confirmed the shut down of its manufacturing facility in Basingstoke, England, resulting in US\$85m to US\$95m in restructuring costs for the company. This is in accordance with the decision of company to cut development costs from US\$1.1bn per drug down to US\$800m. The company has faced crisis as demand for the plant's main products, medicines in tablet and capsule form, has fallen in the face of the increasing importance of injectable medicines. The site produced 56m packs of finished product per year with an annual volume of 1.5bn doses. The facility was responsible for the manufacture of four of Eli Lilly's key drugs like Cialis Evista Strattera and blockbuster antipsychotic, Zyprexa. Approximately 100 employees will be eligible for retirement by the time the site closes and the company is planning to redeploy some employees elsewhere.

UK: Almac expands its formulation plant

Pharma, Solid oral dose product specialist, has announced the expansion of its formulation facilities located at its UK headquarters to provide a wider range of services to pharma and biotech companies. The company has opened a revamped building at its Craigavon site in Northern Ireland, representing an investment of 8m euros and the custom-designed 10,500sq foot facility provides extended formulation development services in solid oral dosage forms from pre-clinical through pilot scale. The company claims it can use just milligrams of active pharmaceutical ingredients (API) to produce supplies for first time in-man (FTIM) studies, or can develop and optimise formulation to progress it through to commercial manufacture. The new facility will ultimately lead to the creation of 60 specialist jobs in Formulation and Development and Analytical Support.

Germany: Sartorius acquires Toha Plast

Sartorius has snapped up all shares in plastics manufacturer Toha Plast. According to the deal, Sartorius has bought up the company, which develops and manufactures plastic components for the medical and biotechnology industries, for an undisclosed sum. The acquisition is effective immediately and this acquisition will support the formulation segment of Sartorius. Toha Plast has been a long-term development partner and supplier to Sartorius, working with the company for over 30 years in thermoplastics processing and injection moulding. By this acquisition, Sartorius aim to expand the expertise of their biotechnology division in the field of plastics, and strengthen their position in biopharmaceutical disposables. The company has been proactively extending its portfolio of disposables through alliances and its own developments in recent years.

Sweden: Orexo enters an agreement to market Rapinyl

Orexo AB and the Hungarian pharmaceutical company Gedeon Richter Ltd. entered into a distribution agreement under which Gedeon Richter receives exclusive rights to market and sell Rapinyl, Orexo's patented product for management of breakthrough cancer pain - in CIS, Bulgaria and Rumania. Rapinyl is a product for the treatment of cancer-related breakthrough pain. It is based on Orexo's unique proprietary technology for sublingual administration, where a fast dissolving tablet is placed under the tongue and the active substance is absorbed through the mucous membrane in the mouth. This new drug form is designed for rapid onset of action and predictable and reproducible pain relief and results in a simplified treatment of patients suffering from breakthrough pain. The referred distribution rights apply to CIS, Bulgaria and Rumania.

Sweden: Pfizer increases Genotropin manufacturing capacity

Pfizer increases manufacturing of Genotropin, a top-selling human growth hormone, to meet the global requirements. The company has invested SEK 1.5 billion in Strängnäs, Sweden that will be home to a new state-of-the-art turnkey factory adjoined to an existing plant. The expansion will boost Pfizer's production capacity of Genotropin used in the treatment of dwarfism and growth failure. According to market researchers Visiongain, Genotropin has come under pressure in recent quarters. Pfizer reported a worldwide 3 per cent decrease in Genotropin sales to US\$586 million for the first nine months of 2006, with more competitors such as Sandoz's Omnitrope (somatotropin) entering the market.

Belgium: Solvay deals with Novasep

Solvay has contracted Novasep to provide synthesis of two active pharmaceutical ingredients, following Novasep's decision to combine synthesis and processing expertise. The deal is an endorsement of Novasep's strategy of combining API synthesis and processing capabilities, with Belgian pharmaceutical firm Solvay applying a strategic shift in outsourcing its manufacturing activities, in a bid to achieve "high quality, competitively-priced alternatives. The manufacturing alliance has taken the form of a five-year agreement, with a possibility of an extension. As part of the agreement, Novasep will implement large-scale production of Pinaverium bromide and Betahistine at their French Mourenx facility. Dicletel is one of Solvay's drugs for irritable bowel syndrome and contributes to their leading position in the market of gastrointestinal spasmolytics, while Serc is the world market leader in the treatment of Ménière's disease and vestibular vertigo.

Spain: Medichem passes third consecutive FDA plant inspection

Medichem has announced it has passed a USFDA inspection without any problem for the third consecutive time. The company, specialised in the manufacture of active pharmaceutical ingredients, has now become part of an exclusive group of pharma companies that completed three consecutive inspections without any observation. The inspection of

Medichem's manufacturing facility located near Girona in Spain was carried out by two FDA officers last month for four days and eight different APIs were part of the inspection. The FDA audited the management of materials, as well as laboratory and quality systems. The USFDA didn't issue a form of 483 as it finds neither deficiencies nor observations have been detected. The company hopes this recognition will be an enthusiastic move to expand their business to newer market places. It has pipeline products that are indicated for the treatment of diseases in many therapeutic areas including central nervous system, cardiovascular, antivirals, antihistamines and antiasthma.

Asia Pacific

China: Peregrine files suit against CTL

Peregrine Pharmaceuticals, Inc. has established a wholly foreign-owned enterprise (WFOE), Peregrine Beijing Pharmaceuticals Technology Development Ltd., in Beijing, China. This subsidiary is expected to give Peregrine the opportunity to leverage the company's products and technology in Chinese market. On the other side, it has filed a lawsuit alleging breach of contract against its licensee, Cancer Therapeutics Laboratories, Inc. (CTL), that has licensed certain rights under the company's Tumor Necrosis Therapy (TNT) technology platform exclusively for development and commercialization in China. The major reasons that led to file were breaches of contract, including failure to provide clinical data to Peregrine from a sublicensing arrangement in China regarding Peregrine's TNT agent, failure to account for a current sublicense agreement with Shanghai Medipharm Biotech despite repeated attempts by Peregrine to obtain evidence of an agreement, and failure to provide accounting of any revenue, equity and data derived from that sublicense agreement.

China: AMDL announces of Levofloxacin production in China

AMDL has confirmed that its Chinese subsidiary, Jade Pharmaceutical Inc., has begun production of the antibiotic levofloxacin, which is part of the top selling class of drugs in China, and which is used to treat bacterial infections including pneumonia, urinary tract, kidney and skin infection. Levofloxacin is marketed in the U.S. by a major pharmaceutical company. Levofloxacin is an advanced generation fluoroquinolone antibiotic and has proven its efficacy and safety globally with more than 12 years of usage. Jade Pharmaceutical recently received approval for the product from the China State Food and Drug Administration. Jade Pharmaceuticals is producing levofloxacin at the Jiangxi Jade Biochemistry Ltd. manufacturing facility in the South China City of Shargro in the Jiangxi Province of China and, will be sold in the People's Republic of China.

Japan: Bristol and Otsuka sign agreement for Diabetes compound

Bristol-Myers Squibb Company and Otsuka Pharmaceutical Co., Ltd. announced that Otsuka has been granted exclusive rights in Japan to develop and commercialize the investigational compound saxagliptin, being studied for the treatment of Type 2 diabetes. Saxagliptin, discovered by Bristol-Myers Squibb, is a dipeptidyl peptidase-4 (DPP-4) inhibitor currently in phase III development in the United States and Europe. Agreement terms include an upfront payment by Otsuka to Bristol-Myers Squibb. Bristol-Myers will receive milestone payments based on certain regulatory events, as well as sales-based payments following regulatory approval of saxagliptin in Japan. Bristol-Myers Squibb also retains rights to co-promote saxagliptin with Otsuka in Japan. Under the licensing agreement, Otsuka will be responsible for all development costs in Japan. Saxagliptin is a DPP-4 inhibitor, a new class of diabetes medicines that work by increasing and prolonging the action of natural hormones in the body called incretins and further mechanisms lead DPP-4 inhibitors to improve timely insulin release and ultimately decrease high blood sugar levels in patients with Type 2 diabetes. Both companies have agreed the terms of the agreement.

National

India: BMC gets AIIMS status

The Centre has selected Bangalore Medical College (BMC) as one of the 13 Medical Colleges in the country to be upgraded to the level of All India Institute of Medical Sciences (AIIMS), New Delhi. It has already sanctioned Rs 100 crore for upgrading this prestigious medical institution. The Bangalore Medical College would be the first to get this status with Rs 100 crore coming from the Centre and the Karnataka government chipping in with another Rs 20 crore. The Centre has already released Rs 10 crore," Karnataka Medical Education Minister VS Acharaya told Pharmabiz

India: PCI for single authority for pharmacy education

Perturbed over the poor state of affairs of the pharma education in the country largely due to the dual regulatory authority, the Pharmacy Council of India (PCI) has urged the central government to put an end to the dual regulatory authority in pharma education in the country by divesting the powers of AICTE in this connection. In a proposal to the Union government, the PCI has urged the central government to delete the word pharmacy from section 2G of the AICTE Act 1987 and thereby give sole authority to the PCI to control pharma education and practice of the profession in the country.

India: Nicholas collaborates with Eli Lilly

Nicholas Piramal India and US-based Eli Lilly and Company have signed a new drug development agreement to develop and, in certain regions, commercialise a select group of Lilly's clinical drugs that span multiple therapeutic areas. This alliance seeks to increase productivity in drug development by synergising the unique strengths of both firms and equitably sharing risk and reward. NPIL will be responsible for the design and execution of the global clinical development program, including IND-enabling non-clinical studies and human clinical trials up to Phase III. NPIL would receive a call-back payment, and potential milestone payments of up to US\$100m, plus royalties on sales upon successful launch of the first compound. This will be a unique partnership, where we will collaborate in the development of new drug candidates and help reduce the burden of disease for patients.

India: Dr.Reddy's to increase its manufacturing capacity

Dr Reddy's Laboratories has boosted its ability to serve Western pharmaceutical markets with an increase in its manufacturing capacity for drug formulations. The company has invested US\$100m to increase its capacity within formulations, active pharmaceutical ingredients (APIs) and custom pharmaceutical services. This will fit in well with the firm's expansion of its manufacturing capacity meant for the EU and the US market. The company based in Hyderabad, has expanded its existing units in Hyderabad and in Vishakhapatnam and may open two more in Hyderabad and Srikakulam district of Andhra Pradesh. For funding purposes, it is planning to use cash raised via a recent placement of American Depository Shares (ADS) that brought in around US\$250m. The sum will be used for corporate purposes, which include geographic expansion, potential acquisitions of, or investments in, companies and technologies that complement our business, capital expenditures for increasing production capacities, addition of new capabilities and so on.

India: Actavis expands business in India

Icelandic pharmaceutical Actavis has snapped up an Indian manufacturing plant in a move to take advantage of lower manufacturing costs for exports to the US and Europe. Actavis has acquired the plant from Southern India-based Grandix Pharmaceuticals for an undisclosed sum. In addition to development and manufacture of products for the US and European markets, the plant will also be used to develop and re-launch older products that require a lower cost base to remain competitive in the international marketplace. The company aims to increase production at the plant from around 700m tablets a year to approximately 4bn over the next eighteen months. On top of this latest purchase, the company has also opened a new active pharmaceutical ingredient (API) development unit in India with the aim to develop 10–15 products a year – the first 10 are already in progress. By establishing this new API facility, the company is aiming to backward-integrate its business, thus gaining control of their supply chain and further reduce input costs.

India: Aurobindo buys Netherlands Pharmacin

Aurobindo Pharma Ltd (APL) has bought the Netherlands-based generic pharmaceutical company, Pharmacin International. To facilitate the buyout it aims to expand its presence in the lucrative European markets. APL has through its wholly owned subsidiary Agile Pharma, Netherlands entered into share purchase agreement with Jerim and Jonghoud International of the Netherlands. Under the terms of the share purchase agreement, Agile Pharma has acquired 100% of the shares of Pharmacin International from Jerim and Jonghoud International. Pharmacin is a profit-making company with a turnover of over 6m euros for the year ending 2006 and a CAGR of over 30%. APL expects to build on these strengths. Its product portfolio, manufacturing and R&D capabilities would bring greater synergy. APL would gain access to several markets in Europe and Pharmacin has warehouses and offices close to Rotterdam, a strategic distribution location in Europe.

India: Ranbaxy acquires stake in Krebs Biochemicals

The drug industry Ranbaxy has acquired a 14.95% stake in Krebs Biochemicals, a strong player in fermentation technology space. The industry picks up 14.95% stake in Krebs biochemical by preference allotment of 10.5 lakh shares to Ranbaxy at Rs 85 per share. The issue of 20-lakh shares warrants to promoters. IPCA labs were also believed to have been in the race. Krebs Biochemicals has interests in Pravastatin & Simvastatin. It has a state of the art manufacturing facility at Vizag. It is a strong player in fermentation.

India: Pharma's largest licensing deal, worth US\$2.1bn

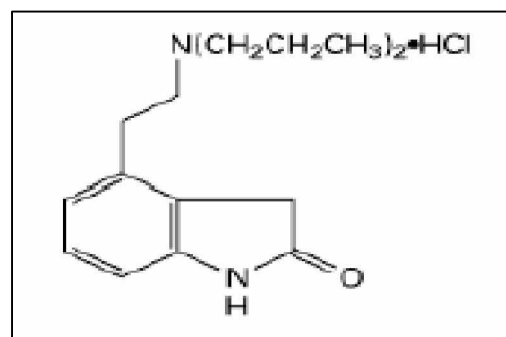
GlaxoSmithKline has signed the world's most expensive licensing deal worth US\$2.1bn with Danish biotech company Genmab. The record breaking agreement provides GSK with commercialization rights to Genmab's human monoclonal antibody HuMax-CD20, which is indicated for certain, types of leukemia and non-Hodgkin's lymphoma. The industry has never witnessed a deal of this size before, the closest in value was a US\$2bn deal signed between Imclone Systems and Bristol Myers Squibb in 2002.

India: Ranbaxy bids for Merck's generics business

Ranbaxy is making a bid to acquire Merck's generic division, which would take at least three years to fully integrate the operations of the two companies. Combining the two entities would give Ranbaxy a product portfolio with over 110 proprietary names covering the high-selling segments like cardiovascular, respiratory and neurological, among others. Besides, Ranbaxy with a little over a billion in turnover would have to borrow heavily to finance the acquisition. Merck's three generic subsidiaries Alphapharm, Genpharm and Dey Inc put together boast of a list of about 70 different proprietary names filed with US FDA, have revenues of US\$2.1 billion and is valued at around US\$5 billion.

Product Focus –Requip (Ropinirole hydrochloride)

Name: Requip
Generic Name: Ropinirole hydrochloride
Manufactured By: GSK
Expiry Status: 2007
Empirical Formula: $C_{16}H_{24}N_2O \cdot HCl$
Molecular Weight: 296.84



Requip, is the first FDA-approved medication to treat moderate-to-severe primary Restless Legs Syndrome (RLS). It is used to treat Parkinson's disease. Parkinson's disease is a disease of the nervous system associated with the trembling of the arms and legs, stiffness and rigidity of the muscles and slowness of movement. It is caused by the progressive loss of brain cells, which produce the chemical dopamine. As the cells die, less dopamine is produced in the area of the brain that co-ordinates movement. Requip belongs to a group of medicines known as dopamine agonists. Dopamine agonists work by increasing the dopamine levels in the brain. This helps to reduce the symptoms of Parkinson's disease.

Chemical Structure

Requip (ropinirole hydrochloride) is an orally administered non-ergoline dopamine agonist. It is the hydrochloride salt of 4-[2-(dipropylamino)ethyl]-1,3-dihydro-2H-indol-2-one monohydrochloride. Ropinirole hydrochloride is a white to pale greenish-yellow powder with a melting range of 243° to 250°C and a solubility of 133 mg/mL in water.

Mechanism of Action

Requip is a non-ergoline dopamine agonist with high relative in vitro specificity and full intrinsic activity at the D2 and D3 dopamine receptor subtypes, binding with higher affinity to D3 than to D2 or D4 receptor subtypes. The exact mechanism of action of Requip as a treatment for Parkinson's disease is unknown, although it is believed to be due to stimulation of postsynaptic dopamine D2-type receptors within the caudate-putamen in the brain.

Indications & dosage

Requip is indicated for the treatment of the signs and symptoms of idiopathic Parkinson's disease. Requip can be taken with or without food. Patients may be advised that taking Requip with food may reduce the occurrence of nausea. However, this has not been established in controlled clinical trials.

Requip–Side effects
Dizziness
Nausea
Drowsiness
Trouble sleeping
Constipation
Stomach pain
Headache

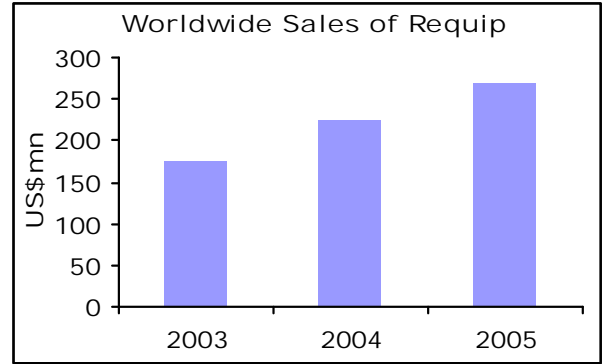
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Indian Pharmaceutical Association
Kalina, Santacruz (E), Mumbai - 400 098.
Tel: 91-22-2667 1072 :: Fax : 91-22-2667 0744,
Email: ipacentr@mtnl.net.in :: www.ipapharma.org

Cygnus Business Consulting & Research
4th & 5th Floors, Astral Heights, Road No.1, Banjara Hills, Hyderabad-500034
Tel: +91-40-23430203-07, Fax: +91-40-23430201,
E-mail: info@cygnusindia.com; Website: www.cygnusindia.com

Market Performance

The worldwide sale of Requip was US\$268.44m in 2005 as compared to US\$223.5m in 2004, representing an increase of 20.1% over the previous year. This could be attributed due to high potential market in USA. In Q1 2006, weekly new prescriptions for the product have quadrupled in the USA since it was launched for restless legs syndrome (RLS) in Q2 2005.



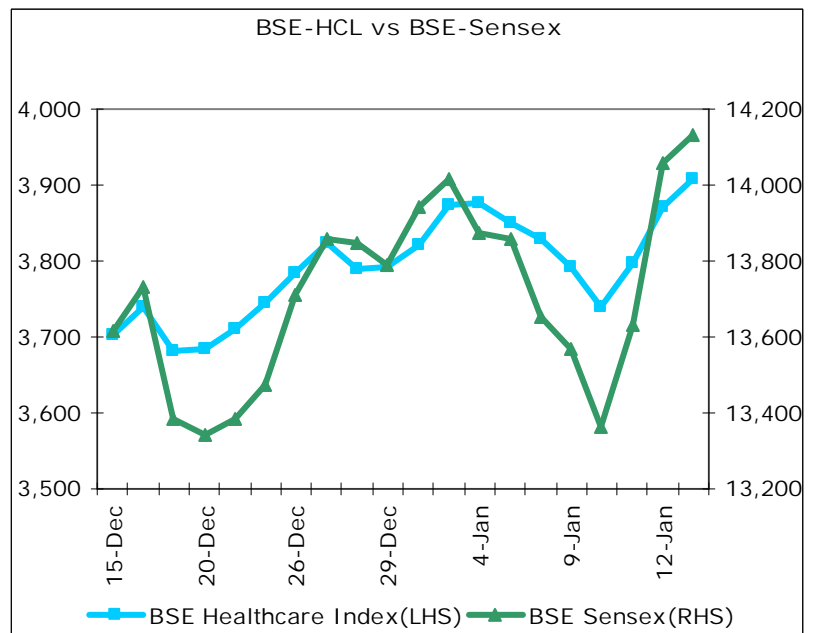
Source: GSK Annual Report

Outlook

In 2005, Glaxo's Requip, a treatment for Parkinson's disease, was approved for restless legs. The compound patent expires in December 2007 and the method of use patent in May 2008. Requip will reach a growth of 23%-25%, as the Parkinson's disease increases. As it is going to be off patent in the next two years, the company will try to achieve more profit by applying promotional activities.

Stock Scan

For the period of Dec 15, 2006 to Jan 15, 2007, BSE Healthcare index moved in tandem with BSE Sensex. On Dec 15 BSE healthcare index was at 3,701.91 points whereas the BSE index was 13,614.52 points. BSE sensex recorded both upward and downward trend in this period and the healthcare index performed the same. On Dec, 20, the healthcare index recorded a decrease to 3684.38 points, whereas the sensex lost 41.80 points to 13,340.21 points, compared to the pervious day closing. Healthcare index again went up to 3,822.65 points, whereas the sensex was up by 151.35 points to 13,859.69 points. On Jan, 15, the BSE healthcare index was at 3,908.73 points which was up by 37.17 points, whereas the BSE sensex was at 14,129.64 points which was up by 73.11 points as compared to the pervious day closing.



Regulatory Issues

INTERNATIONAL

USA: Regulatory filings submitted for key chronic indications

AstraZeneca has submitted Exant the first oral direct thrombin inhibitor, for regulatory review in the EU and US in key chronic-use indications. In the US, submissions have been made to the Food and Drug Administration (FDA) for Exanta in the prevention of stroke and other thromboembolic complications associated with atrial fibrillation (AF) and long-term secondary prevention of venous thromboembolism (VTE), after standard treatment for an episode of acute VTE. In Europe, regulatory submissions have been made to the Reference Member State, France, as part of the Mutual Recognition Procedure for use of Exanta in prevention of stroke and other thromboembolic complications associated with AF and the treatment of VTE.

USA: Par receives final approval from FDA

Par Pharmaceutical Companies, Inc. has received final approval from the USFDA for its Abbreviated New Drug Application (ANDA) for ondansetron orally disintegrating tablets (ODT) in 4 mg and 8 mg strengths. Par has been awarded 180 days of marketing exclusivity for being the first to file an ANDA containing a paragraph IV certification for the product, which will be marketed by Pliva, Inc., the U.S. subsidiary of Pliva d.d., which is a subsidiary of Barr Pharmaceuticals. Ondansetron ODT is the generic version of GlaxoSmithKline's Zofran ODT(R). The product is used for the prevention of nausea and vomiting associated with highly emetogenic cancer chemotherapy and with initial and repeat courses of moderately emetogenic cancer chemotherapy, certain radiotherapies, and the prevention of postoperative nausea and/or vomiting. Annual U.S. sales of Zofran ODT(R) are approximately US\$300 million.

USA: FDA approval for Pamine tablets

The USFDA has granted final approval for the Boca Pharmacal's Abbreviated New Drug Application (ANDA) to market its generic version of Kenwood Therapeutics Pamine(R) (Methscopolamine Bromide) Tablets, 2.5 mg and Pamine(R) Forte (Methscopolamine Bromide) Tablets 5 mg. The Company plans to launch its product immediately. These tablets are indicated for the treatment of adjunctive therapy for the treatment of peptic ulcer. The company expects that Methscopolamine Bromide will be the first of many approvals over the next twelve months. It is planning to patent and market the coming blockbuster.

USA: Depressive disorder drug approved

The USFDA has approved the first generic version of Wellbutrin XL (Bupropion hydrochloride) Extended-Release Tablets, which are indicated for the treatment of major depressive disorder (MDD). The approval is an important step in the agency's effort to increase the availability of lower-cost generic medications. Wellbutrin XL was the 21st highest-selling brand-name drug in the United States in 2005, with sales estimated at US\$1,326.4m. FDA received a citizen petition (a formal request for FDA action) that asked FDA to consider several issues for bupropion hydrochloride extended-release tablets, including how similarly the drug is absorbed into the bloodstream. Bupropion Hydrochloride Extended-Release Tablets, 150 mg and 300 mg are manufactured by Anchen Pharmaceuticals Inc, of Irvine, CA.

National

State FDA cancels product license of Wockhardt's Wosulin 50:50

The Food and Drug Administration (FDA), Maharashtra has cancelled the product license of Wosulin 50:50, the human recombinant insulin mixture suspension form of Mumbai based Wockhardt Ltd., for finding discrepancy in description on label of the product. According to FDA sources, the action was taken last month, after having enough communication with the company. According to reports from the in-house drug

testing laboratories of FDA the insulin product, which should be in suspension form, was found to be a clear solution. The action is only on the suspension form Wosulin 50:50, it is learnt.

Govt increases abatement rate to 42.5%

The Government of India has increased the abatement rate for drugs while calculating excise duty on MRP from 40 per cent to 42.5 per cent, according to a notification issued by the Ministry of Finance recently. As per the notification, the Central government has made the significant amendment in its notification dated January 7, 2005, by the Ministry of Finance (Department of Revenue) No. 2/2005-Central Excise (N.T.), to enhance the abatement rate to 42.5 percent. The new rate is applicable in calculation from February 1, 2007.

Upcoming Events

1.	Event	Smart Lab Exchange 2007
	Date	Feb 27 - 28, 2007
	Venue	Millennium Mayfair, London, UK
	Highlight	Solutions and strategies for long-term archiving of electronic data. Data management for biological laboratories Strategies for achieving lean, manageable IT infrastructures Integration of laboratory management systems with ERP systems Managing the validation effort required for deployment of new systems and upgrades Best techniques for achieving global collaboration and information sharing across an enterprise.
	Contact Details	The Organizing Secretary, Millennium Mayfair, London, UK Tel: 0800 652 2363 ; Email: enquire@iqpc.co.uk ; Web: www.iqpc.co.uk
2.	Event	FDA's Pharmaceutical Quality Initiatives Implementations
	Date	Feb 28 - Mar 2, 2007
	Venue	Bethesda North Marriott Hotel and Conference Center, Bethesda, Maryland
	Highlight	Explore FDA's quality initiatives and share progress made since the issuance of the Agency's 2004 report, "Pharmaceutical cGMPs for the 21st Century – A Risk-Based Approach". Provide updates from the FDA's Council on Pharmaceutical Quality, with a focus on implementation challenges and remaining issues. Seek input and recommendations from stakeholders.
	Contact Details	The Organizing Secretary, AAPS General meeting North Bethesda, MD PO Box 590 Frederick, MD 21705 Tel: Phone: (703) 243-2800; Fax: (301) 694-5124 Email: Meetings@aaps.org ; Web: www.aaps-ispe.org ;
3.	Event	2007 GPhA Annual Meeting
	Date	Mar 1-3, 2007
	Venue	The J.W. Marriott Desert Ridge Resort and Spa, Phoenix, Arizona
	Highlights	Distinguished speakers provide attendees with the latest information on business aspects of the current healthcare environment, as well as perspectives on role for generic medicines in 2007 and beyond. GPhA Annual Meeting provides a unique opportunity to network with national and international business, government and policy leaders as well as top decision makers in the growing U.S. generic pharmaceutical industry.
	Contact Details	Jennifer Sunshine, Organizing Secretary, Tel: 703-647-2485; E mail: jmay@gphaonline.org ; Web: www.gphaonline.org
4.	Event	1st Annual FDA/DIA Statistics Forum
	Date	Mar 5-7, 2007
	Venue	Doubletree Hotel Bethesda, Bethesda, MD, USA

	Highlights	Adaptive Designs – Regulatory Issues, Concerns and Experience; Drug Safety Evaluation to meet Challenges of 21st Century Expectations What pharmaceutical industry and regulatory agencies can do differently? Non-inferiority associated with Clinical Trials and Statistics
	Contact Details	Ellen Diegel, Organizing Secretary, % DIA, 800 Enterprise Road, Suite 200, Horsham, PA 19044, USA Tel: +1-215-442-6100; Fax: +1-215-442-6199; E-mail: Ellen.Diegel@diahome.org; Web: www.diahome.org;
5.	Event	Drug Discovery Technology Europe 2007
	Date	Mar 12-15, 2007
	Venue	Novotel London West, UK
	Highlights	The event focuses on improving productivity by changing processes, creating a seamless approach to the different drug discovery processes, using expensive shiny equipment in new ways to maximise and Improve decision-making at an earlier stage to reduce waste for drugs.
	Contact Details	To the Secretary, Novotel London West One Shortlands, London, UK W6 8DR Tel: +44(0)20 8741 1555 Fax: +44(0) 20 8741 21208 Web: www.novotellondonwest.co.uk, Email: H0737@accor.com
6.	Event	Bio- Square 2007
	Date	Mar 12-14, 2007
	Venue	Lyon, France
	Highlights	Meetings with Pharma executives, investors and biotech companies for analyzing new industry trends and discuss how biotechnology companies can face current market challenges.
	Contact Details	Karen Hilaire, The Organizing Secretary Tel: +33 (0)4 78 92 70 13 Email: karen.hilaire@biosquare.com; Web: w.biosquare.com
7.	Event	European Bulk and Speciality Chemical Supply Chain Conference
	Date	Apr 16 – 18, 2007
	Venue	Hilton Düsseldorf, Düsseldorf, Germany
	Highlights	It's the only opportunity to learn from over 25 real-life logistics case studies from chemical manufacturers, on the same topics and challenges that face on a day-to-day basis. Most of the strong audience is fellow supply chain executives at chemical manufacturers, meaning it is the only opportunity to have meaningful discussions on biggest supply chain challenges. It's the only event that is produced and developed closely with an Advisory Board of 6 leading chemical supply chain practitioners. Logi Chem is quite simply designed by the industry, for the industry, to the critical needs.
	Contact Details	Josephine Andrews, Organizing Secretary Tel: 44 207 368 9465 E mail: logichem@wbr.co.uk; Web: www.wbr.co.uk
8.	Event	3rd Pharmaceutical Science World Congress (PSWC 2007)
	Date	Apr 22-25, 2007
	Venue	RAI Congress Center, Amsterdam, The Netherlands
	Highlights	The 3rd world conference is devoted to the global developments. The PSWC2007 will cover a broad spectrum of topics from basic to applied and clinical sciences, addressing timely issues of great importance to drug discovery, development, and regulation & medication management. An exhibition in attention to the future generation of pharmaceutical scientists through poster and podium presentations, as well as a pre-conference meeting for graduate students and post-doctoral fellows would also be conducted.

	Contact Details	The Organizing Secretary P.O. Box 84200, 2508 AE the Hague, the Netherlands Tel: +31 (0) 70-302 1981, Fax: +31- (0) 70 -3021 1988 Email: pswc@fic.org, Website: www.fip.org
9.	Event	Superbugs & Superdrugs
	Date	Apr 23-24 2007
	Venue	Crowne Plaza Hotel - The City, London, UK
	Highlights	The conference discusses on antimicrobials and their resistance, complex procedures for getting drugs through regulatory hurdles, R&D pipeline and novel advances in drug development.
	Contact Details	SMi Group Ltd Unit 122, Great Guildford Business Square 30 Great Guildford Street London, SE1 0HS, United Kingdom. Tel: +44 (0) 20 7827 6000 ; Fax: +44 (0) 20 7827 6001 E-mail : smiproduction@smi-online.co.uk; Web : www. smi-online.co.uk
10.	Event	Drug Discovery and Development Partnering, Licensing and R&D Innovation Summit JAPAN
	Date	Apr 25-27, 2007
	Venue	Tokyo, Japan
	Highlights	It provided a meeting place for attendees from Japan, US, Europe and Asia-Pacific to evaluate global R&D strategies and commercial opportunities to find partners and compounds for Licensing, and how the companies can market their drugs in Japan more efficiently and take the advantage of emerging markets.
	Contact Details	The Organizing Secretary, IBC USA Conferences, Inc P.O. Box 414525 Boston, MA 02241-4525, USA, Tel: (+1) 800-390-4078 Email: custserv@ibcusa.com Web: www.ibclifesciences.com