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In Focus: Contract Research and Manufacturing Services (CRAMS)

Introduction

Contract research began in the late 1940s, with businesses offering preclinical toxicology studies on a contract basis. By 80s some CRO started providing all of the development services typically found in a major pharmaceutical company resulting in outsourcing the entire product development services. By early 90s, specialized services like clinical trials management (drug packaging, labeling), trial monitor staffing were seen. Some of the organizations provide all these services under one roof, and called as Contract Service Organization (CSO) rather than what are traditionally called as CRO.

Mounting R&D cost pressures, declining productivity on the drug discovery front, impending patent expirations (resulting to pinching generic penetration), escalating pricing pressures and the ultimate falling profitability have made Contract Research and Manufacturing Services (CRAMS) an inevitable option for global pharma peers. Global pharma innovators are under tremendous pressure to contract out the non-core and uneconomical research and manufacturing services to third parties operating at a relatively lower cost structure in the emerging countries like India, China.

Deteriorating profitability at the innovative players end would continue to provide a major boost to outsourcing of pharma activities to low cost offshore destinations like India and China. India, driven by its intrinsic competitive advantages like – low cost manufacturing, large pool of research talent and adequate research capability - has already proved to be one of the most preferred outsourcing destinations for global pharma space. Currently India's contribution to the global CRAMS markets accounts to about 3% and this is expected to reach 10% in the next 10 years.

Increasing growth challenges, sharper focus on improving operational efficiencies and improvement of profitability are the ultimate thrust area for the global pharma leader, the top-five factors that contribute to the outsourcing decision among pharmaceutical and biotech firms include quality, timeliness, confidentiality, good manufacturing practice capability, and relationship. These five factors all rank significantly ahead of cost considerations.

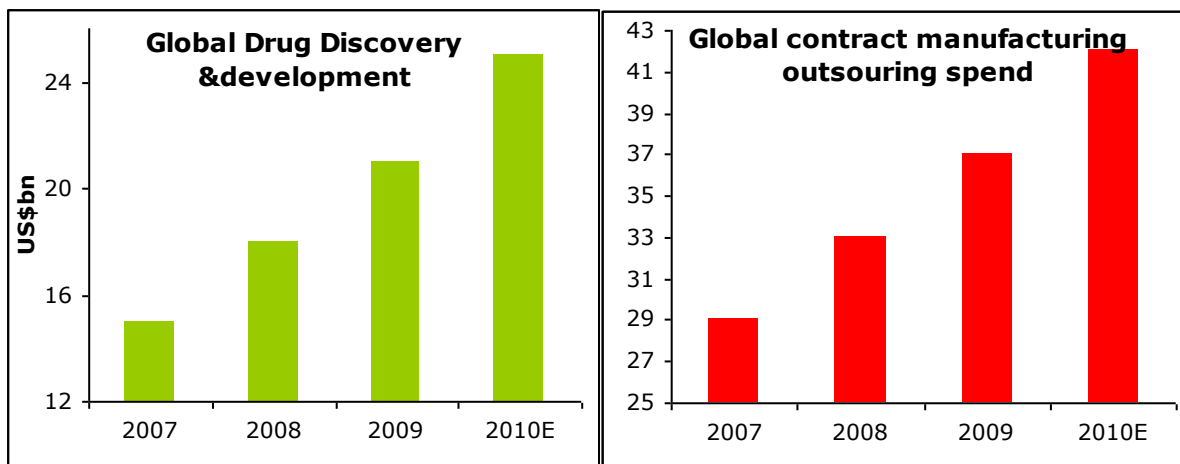
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Global Scenario

Globally pharmaceutical outsourcing is on the rise with large global pharma companies facing the vagaries of pipeline surges and slowdowns, internal consolidation, and global expansion. The global pharmaceutical outsourcing market was worth US\$58 billion in 2009. It is expected to reach US\$67 billion by 2010, growing at a CAGR of over 15% (2007–2010). The global contract research market was US\$21 billion in 2009 and is expected to touch US\$25 billion, reflecting a CAGR of around 18.6% (2007–2010). The contract manufacturing segment of global pharmaceutical outsourcing market was at US\$37 billion in 2009 accounting for the major share (approximately 63.8%) of the total market.



Source; OOPi-E&Y; Cygnus Research

Contract Research

The global contract research market reached at US\$21 billion by 2009, increased by 14% from US\$18.19 billion in 2008. It is expected to grow at an annual rate of 14-16% to reach US\$25 billion through 2010. The market is highly fragmented and the number of CROs worldwide has reached over 1100 despite continued consolidation. Of the large, global contract research providers, Quintiles is the market leader, with 14% of the global market share; followed by Covance and PPD, holding 10% each. The five largest CRO have increased their market share and hold 45% of the total market. CRO provide substantial global capacity to drug developers and have become critical contributors to clinical trial activity. Clinical trials conducted by CRO are completed up to 30% more quickly than those conducted in-house by Pharma companies.

Contract Manufacturing

The global pharmaceutical Contract Manufacturing Outsourcing (CMO) market in 2009 was US\$37 billion; it is expected to reach US\$42 billion by 2010 at a CAGR of 13% (2007–2010). Chemical synthesis constituted close to 60% of total work outsourced in the global contract manufacturing market. India serves global clients through various business models and offerings, such as outsourcing of services (including R&D) and manufacturing. Strong reverse-engineering skills, a robust talent pool, government support for exports, low production and R&D costs, and world-class infrastructure to assure high quality standards are some of the factors enable India to play a pivotal role in the global pharmaceutical market.

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India Scenario

Indian companies with adequate research and manufacturing capabilities are well positioned to benefit from the aggressive cost cutting and outsourcing initiatives of global pharma leaders. Domestic players like Divis, Dishman, Jubilant, Piramal healthcare have already been identified by global innovators for strategic long term contracts. The aggressive headways by Indian CRAMS peers in acquiring international assets (particularly regulated markets like US & Europe) would consolidate the position of India in the global CRAM Space. In order to scale up rapidly and have adequate infrastructure in place, the domestic CRAMS peers have strategically added international assets in the CRAMS space. The rationale behind the acquisitions have been: -

- To leverage on existing client relationships of acquired companies in developed world
- To widen the area of service to the entire life-cycle of pharma product.
- To gain access to newer technology platforms for high-end custom synthesis and clinical research work and new clients.

Government support critical to CRAMS companies

Earlier there was some reluctance to award contracts to Asian pharma manufacturers because of concerns of IP and regulatory compliance. But now some of the Asian countries are changing and becoming very competitive in pharma manufacturing. India is being promoted heavily as an outsourcing hub in the field of CRAMS and much of this is based on a supportive attitude of the Government. In a significant move, the government of India has slashed the tax levied on pharma products manufactured in the country by 50%, reduced the federal value added tax by 2% and extended tax concessions to the pharma and biotech research companies which take up outsourced research works. Some of these measures are likely to spur the growth of the Contract Research and Manufacturing Services (CRAMS) sector in India.

Future Outlook

The Indian market represents a unique proposition for pharmaceutical multinationals temper their ambitions with realism. These multinationals need to focus on realistic pricing and rely on volume sales to capture the vast market (with its potential size being only a little larger than that of the pharmaceutical market in France or Germany) and deliver profits to their doorsteps, at least for the next 20 years. The country is yet to pick up the concept of CROs in its full sense and understand the importance of it; earlier the companies were bit skeptical about sharing information with an outsider. But, it is changing slowly.

The Patent Amendment Act, 2005 was ratified but there are many challenges that the new legislation does not address, including the potential for delays to the period required for granting a patent and discrimination against mail box applications. Indian CROs, taking a cue, are striving to achieve these goals. Increasingly they are becoming competent in all relevant fields through incorporating global standards like GCP and GLP in the truest sense of the term.

While outside India, private institutions are actively engaged in taking up contract research in a multi-stage activity towards development of a transgenics/vaccine/drug or therapeutic, in India the strength may lie in public funded institutions. Hence, contract research may shape up differently in the country. It is, therefore essential to identify different steps involved in development of a drug, transgenic or biological and work on strategies to involve industries/institutions for specific roles.

The global CRAMS market is expected to grow further to US\$85 billions approximately by 2012. Degrowth witnessed in 2009-10 was an aberration due to the global economic slowdown. Shift of CRAMS business from developed countries to developing countries will continue as the innovator companies will lose patent protection for many of their blockbuster drugs in the next couple of years forcing them to look for various alternatives such as, cost control, introduction

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of generics to their portfolio. Financial year 2009-10 was characterized by lower demand, especially for CRAMS players, due to inventory rationalization by major pharma companies and reduction in R&D budgets due to global recession and mergers between major pharma companies. This resulted in less order for contract manufacturing and contract research.

The global CRAMS market in 2010 is estimated to be US\$67 billion and is likely to touch US\$85 billion in 2012 with a CAGR of 14% from 2007-2012. The Indian CRAMS market stood at US\$3.8 billion in 2010, and is estimated to reach US\$7.6 billion by 2012, growing at a CAGR of 47.2% (2007-2012).

The industry experts estimate that CMO business may rise to US\$7-8 billion in the next four to five years as it is growing at more than 40% over the next two years. Indian companies are well equipped to capitalise on this opportunity. They have strengthened their presence in the market by acquiring better technologies and developing expertise in niche segments that offer higher margins and have higher entry barriers. India could potentially account for 30-40% of the outsourced market share for APIs, finished dosage formulations and intermediates in the coming years.

MNC pharma companies are increasingly focusing on realigning their manufacturing activities in order to concentrate on core activities such as R&D and brand building—thereby reinforcing the potential for cost savings through contract manufacturing. The aggressive outsourcing strategies outlined by major players like AstraZeneca would significantly enhance the medium-to-long term growth outlook. There has been a perceptible increase in the size and quality of deals across in the industry e.g. BMS-Syngene, Jubilant-Syngenta, NPIL-Eli Lilly.

Under pressure to protect their margins, global pharma companies are outsourcing non-core activities like manufacturing of intermediates and APIs to low-cost destinations such as India. This trend is likely to gain momentum over the next decade. Making APIs and oral solid formulations (tablets and capsules) will continue to be the major source of revenue for India's contract manufacturing industry in coming years. India, with its inherent competitive advantages, stands as one of the most preferred outsourcing destinations for a range of activities and is now becoming a critical part of manufacturing and drug development value chain of various global innovator pharma companies.

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News Briefs

MARKETING

Americas

USA: BioTime to launch seven new embryonic progenitor cell lines

Bio Time, Inc. has launch seven new human embryonic progenitor cell lines and seven novel culture media for these lines. These progenitor lines were produced from embryonic stem cells using the company's ACT Cellerate technology. Human embryonic progenitor cells are intermediate in the developmental process between embryonic stem cells and fully differentiated cells. The cells possess the ability to become a wide array of cell types with potential applications in research, drug discovery, and potential novel regenerative stem cell therapies. The seven new cell lines have markers of diverse mesoderm and neural crest cell types and are designated W11, Z2, SK31, SM35, T36, EN51, and EN55.

USA: SCOLR Pharma signs pact with Emerson Group to provide sales support

SCOLR Pharma, Inc. has signed an agreement with The Emerson Group to provide sales support for the company new line of extended-release nutritional and over-the-counter (OTC) drug products. The Emerson Group will provide strategy consulting, sales, distribution, logistics and account management services in support of SCOLR new line of extended-release nutritional and over-the-counter drug products, which utilize the Company's proprietary controlled delivery technology. The Emerson Group has experience with virtually every over-the-counter category and a well established record of success in building overall sales and visibility with retailers.

Asia-Pacific

India: Indegene rides on global drug majors' marketing spend cuts

The outcry over the Obama-Ohio bid to oust offshoring is still ringing in infotech circles. Western drug majors are increasingly looking at India these days as they go about cutting their large spend on sales and promotion. 'Big Pharma' is known to spend a chunky 30% of its revenues to promote and sell its drugs. Some US\$6-7 billion a year goes into 'medical education' alone for interacting with doctors and patients through sales forces. Indegene Lifesystems Pvt Ltd, Bangalore, is the largest spend, topping what companies keep aside for research and development or finding new drugs; now each of them seeks to cut by US\$100-150m. In recent years, multinational pharma companies, which until now thought nothing about spending US\$300m on doctor meetings alone, have sought to do this differently and cut US\$100m in expenses.

Cipla launches world's first generic pirfenidone in India

Cipla has launched pirfenidone in India under the brand name pirfenex, for the treatment of Idiopathic pulmonary fibrosis (IPF). Pirfenidone is a novel anti-fibrotic drug which through clinical trials has shown to slow down progression of this terminal disease and stabilise lung function. A chronic progressive form of lung disease, IPF has average survival rates as low as three to five years which is less than many cancers. Till now there is no approved treatment for IPF. Cipla technical prowess along with leadership in terms of range of drugs and therapeutic categories in the respiratory segment, is leading the fight to provide world class affordable treatment for patients with orphan diseases.

INVESTMENT

EUROPE

Switzerland: Novartis receives regulatory approval for Gilenya in Russia

The Russian health authority, the Federal Service on Surveillance in Healthcare and Social Development, has granted approval for Gilenya (fingolimod) 0.5 mg once-daily oral therapy for the treatment of relapsing remitting multiple sclerosis (MS). Russia is the first country to approve Gilenya, providing a new

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treatment option offering significant efficacy for patients in the convenience of an oral capsule. Approximately 85% of patients with MS are estimated to have the relapsing remitting form at the onset of disease. Novartis expects to launch Gilenya in Russia in early 2011.

Asia-Pacific

India: Ranbaxy begins operations at new SA facility, invests US\$30m

Ranbaxy (S.A.) Pty Ltd (Ranbaxy S.A.) has commenced operations at its new state-of-the-art manufacturing facility, Be-Tabs Pharmaceuticals Manufacturing Plant, at Roodepoort, Johannesburg, South Africa. The new facility, built with an investment of US\$30m will manufacture analgesics, cold, cough and flu preparations, anti-histamines, anti-hypertensives, CNS drugs, vitamins and minerals as well as a comprehensive range of over-the-counter medication. The products manufactured will comprise tablets and hard gelatin capsules will be supplied to current registered regions.

MERGER & ACQUISITION

Americas

USA: Pfizer to acquire foldRx Pharmaceuticals

Pfizer Inc. and FoldRx Pharmaceuticals have entered into an agreement under which Pfizer will acquire FoldRx. FoldRx portfolio includes clinical and pre-clinical programmes for investigational compounds to treat diseases caused by protein misfolding, which is increasingly recognized as an underlying cause in many chronic degenerative diseases. The company's lead product candidate, tafamidis meglumine, is in registration as an oral, disease-modifying therapy for TTR amyloid polyneuropathy (ATTR-PN), a progressively fatal genetic neurodegenerative disease, for which liver transplant is the only treatment option is currently available. FoldRx has filed a marketing authorization application (MAA) for tafamidis with the European Medicines Agency, and is currently in communication with the FDA to define its pathway for filing in the US.

EUROPE

Switzerland: Lonza acquires viral vaccine & vector manufacturer Vivante GMP Solutions

Lonza enters the viral based-manufacturing market with its purchase of Vivante GMP Solutions, Inc. The acquisition advances Lonza strategy to broaden its biologics custom service offering for the growing viral vaccine and gene therapy markets. The company's viral-vaccine production services will be enhanced by Lonza established expertise in expression technologies and large-scale manufacturing platforms. Additionally, Vivante experience with pre-clinical through late-stage supply of viral vector-based products will compliment Lonza's growing cellular and gene therapy process development and manufacturing capabilities.

France: HRA Pharma, Watson expand marketing partnership

HRA Pharma develops healthcare solutions in reproductive health and endocrinology and makes them available worldwide, and Watson Pharmaceuticals, Inc., a leading global specialty pharmaceutical company have entered into a licensing agreement for the commercialization of HRA Pharma next generation emergency contraceptive ulipristal acetate in Canada. This agreement marks the next step for the commercialization of ulipristal acetate in North America and the second collaboration between the two companies in the field of reproductive health. Recently, the US Food and Drug Administration (FDA) approved ulipristal acetate, which Watson will market in the US under the name ella, as a prescription-only emergency contraceptive. HRA Pharma plans to file a New Drug Submission for ulipristal acetate with Health Canada before the end of 2010

Middle East

Essilor to acquire 50% of Shamir Optical

Shamir Optical Industry Ltd have signed an agreement whereby Essilor will, through a series of transactions, acquire 50% of Shamir Optical. As a result of these transactions, Kibbutz Shamir and Essilor will each own 50% of Shamir Optical. Shamir Optical reported 2009 revenues of US\$142 million, generated mainly in Europe and the United States, and has approximately 1400 full-time employees.

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Amos Netzer. This venture places Shamir Optical in a position to accelerate the development of new products and to strengthen its presence in the market place by using Essilor R&D capabilities, notably in coatings, and its worldwide distribution network. The transaction will create synergies and provide Shamir Optical with additional resources to invest in its development.

Tekmira & collaborators get US\$2.4 mn NIH grant to develop RNAi therapeutics

Tekmira Pharmaceuticals Corporation, a leader in RNA interference (RNAi) therapeutics, with collaborators at The University of Texas Medical Branch, it has been awarded a new United States National Institutes of Health (NIH) grant to support research to develop RNAi therapeutics to treat Ebola and Marburg haemorrhagic fever viral infections using Tekmira's lipid nanoparticle (LNP) delivery technology. The grant, worth US\$ 2.4 million, will support work at Tekmira and the University of Texas Medical Branch at Galveston, Texas. Company are pleased to receive this NIH grant with company collaborators at the University of Texas Medical Branch, who are leaders in the field of hemorrhagic fever virus research. This work builds upon our recently published work, where we reported that our TKM-Ebola product candidate provided complete protection of non-human primates from a lethal dose of Ebola virus.

Asia-Pacific

Phytogen Pharma seeks to expand partnerships

Phytogen Pharma (India) Pvt. Ltd is exploring more marketing alliances in India and abroad for its range of plant-based formulations. Although it has struck a couple of collaborative deals, the company intends to expand its alliances to tap the nascent nutraceutical space which is brimming with lucrative opportunities. Current Indian nutraceutical market is valued at Rs30 billion of which, only 1% is addressed. So far no single player has been able to create a dent in the space. This is where aggressive consumer education needs to happen. Company are gearing up to be a forerunner in the space and are looking at marketing partners who would integrate consumer education in the sales strategy.

EXPORT & IMPORT

Asia-Pacific

India: Pharmexcil pact with DIA

The Pharmaceuticals Export Promotion Council (Pharmexcil) has entered into a memorandum of understanding with Drug Information Association (DIA). The objective of MoU is to exchange information on regulatory and technical aspects and to organise joint programmes related to global drug registration, requirements and clinical research procedures, among others. The DIA is a professional association of over 18,000 members worldwide involved in the discovery, development, regulation, surveillance or marketing of pharmaceuticals or related products.

RESEARCH & DEVELOPMENT

Asia-Pacific

India Vaccine makers to share know-how

Vaccine manufacturers from the developing nations are evolving a strategy to share know-how and intellectual property even as they are focussing on further bringing down costs. 11th Annual General Meeting and conference of DCVMN, manufacturers from developing nations contribute to about 75% of supplies to agencies such as UNESCO and continue to play a critical role in bringing down the cost of vaccines. In fact, some of the vaccines are priced less than a bottle of water in a country like India. The network is engaged in dialogue with policymakers of various developing countries to convince them to take decisions and increase the number of vaccines for usage.

USFDA Approrval

Sun Pharma subsidiary receives US FDA warning, gets approval for generic Strattera caps

Sun Pharmaceutical Industries, Inc, (SPI Inc) has received a warning letter from the United States Food and Drug Administration (USFDA). Letter was issued by the US FDA as a follow up to the last inspection of the SPI Inc manufacturing facility in Cranbury, New Jersey, US, initiated in February 2010 during

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which the US FDA had identified violations of cGMP regulations. SPI Inc has undertaken immediate corrective actions. SPI Inc intends to respond promptly and timely to the US FDA within fifteen working days. SPI Inc is committed to working cooperatively and expeditiously with the US FDA to resolve the matters indicated in its letter.

Reckitt Benckiser Pharma receives US FDA nod for Suboxone sublingual film

Reckitt Benckiser Pharmaceuticals Inc has received approval from the US Food and Drug Administration (FDA) for its New Drug Application (NDA) to manufacture and market Suboxone sublingual film. Suboxone sublingual film has been developed through an exclusive agreement with MonoSol Rx, utilising its proprietary Pharm Film technology, to deliver the opioid dependence treatment Suboxone in a fast-dissolving sublingual film. Suboxone sublingual film is indicated for maintenance treatment of opioid dependence and should be used as part of a complete treatment plan to include counselling and psychosocial support. Prescription use of this product is limited to physicians certified under the Drug Addiction Treatment Act 2000.

Roxane Labs gets US FDA approval to market Losartan tablets

Roxane Laboratories received approval for its Abbreviated New Drug Application (ANDA) for Losartan Potassium Tablets USP, 25mg, 50mg and 100mg as well as Losartan Potassium and Hydrochlorothiazide Tablets, 50mg/12.5mg and 100mg/25mg by the US Food and Drug Administration. Both products are available for immediate shipment to wholesalers and pharmacies nationwide. Roxane Laboratories Losartan Potassium Tablets USP are AB rated to Cozaar (losartan potassium) tablets while Losartan Potassium and Hydrochlorothiazide Tablets are AB rated to Hyzaar (losartan potassium and hydrochlorothiazide) tablets. Annual sales of Cozaar are approximately US\$ 940.2 Million while annual sales of Hyzaar are approximately US\$ 670.7 Million. Roxane Laboratories is located in Columbus, OH in a modern 500,000 square foot manufacturing and laboratory facility.

Sun Pharma subsidiary gets US FDA tentative nod for generic Stalevo

Sun Pharmaceutical Industries Ltd. has granted its subsidiary a tentative approval for its Abbreviated New Drug Application (ANDA) to market a generic version of Orion's Stalevo tablets. These generic carbidopa, levodopa and entacapone tablets contain carbidopa, levodopa entacapone and 25/100/200 mg, and 37.5/150/200 mg. Generic carbidopa, levodopa and entacapone tablets are indicated in the treatment of Parkinson's disease. These strengths of Stalevo have annual sales of approximately US\$ 95 million in the US.

GSK takes 18% minority stake in newly formed Convergence Pharma

GlaxoSmithKline plc has taken an 18% minority equity stake in Convergence Pharmaceuticals Limited, a new biotechnology company will focus on the development of new analgesic compounds. Convergence Pharmaceuticals, which was officially launched, recently raised around US\$35.4 million in Series A financing from a syndicate of leading European and US life science investors. Under the terms of the agreement, Convergence Pharmaceuticals has acquired two clinical stage assets from GSK together with rights to certain earlier stage compounds and contributions in kind. In return, Convergence Pharmaceuticals has issued shares to GSK to the value of US\$4.7 million. These two clinical stage compounds, formerly GSK1014802 and GSK2197944, target voltage-gated ion channels. GSK will also be eligible to receive additional shares on completion of asset milestones. In addition, GSK has taken up an observer role on the board of Convergence Pharmaceuticals

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Extavia (interferon beta-1b)

Introduction

Extavia is a branded version of interferon beta-1b, which is a first-line disease-modifying therapy for treating Multiple Sclerosis (MS). The drug is indicated for the treatment of MS patients with relapsing forms of the disease and for newly diagnosed patients. The active ingredient of the drug, interferon beta-1b is in direct competition with other betaferons such as Bayer Schering's Betaseron, Biogen's Avonex and Merck Seronos Rebif. The active ingredient of the drug slows disease progression in some patients. Major markets for MS therapy are Canada, the US, Germany, Norway, Hungary, and the UK. MS is slowly spreading its reach in the Asian regions. Asia can be a potential market in future.

The drug treats multiple sclerosis

The drug is the first in a new portfolio of medicines from Novartis is planned to include both established treatments and innovative therapies for patients with MS. MS is one of the most common disorders of the central nervous system in young adults. It is a progressive and debilitating disorder caused by the destruction of myelin, which helps neurons carry electrical signals in the brain. As a result, MS causes problems with muscle control and strength, vision, balance, sensation and cognitive functions. MS occurs in elapsing forms involving acute self-limiting attacks of neurological dysfunction (or "relapses") followed by complete or partial restoration of functions. Gender has become a dominant factor in MS during the last decades. The studies have proved MS prevalence rate is higher in women than man, but the cause of the disease has not been found.

Drug Details	
Drug Brand Name	Extavia
Active Ingredient	Interferon beta-1b
Company Name	Novartis
Tentative Approval Date	19th August, 2009
Chemical Type	Existing Molecular Entity
Administration type	Injection
Patent Rights	Yes
Patent Expired	2012

Side effects

The drug is a novel, once-daily oral MS treatment, fingolimod which is a widely used injectible drug. Extavia should be used with caution in patients with depression. Injection site necrosis has been reported in 4% of patients in controlled trials. Typically, injection site necrosis occurs within the first four months of therapy. Necrosis occur at a single injection site or multiple injection sites. Patient understanding and use of aseptic self-injection techniques and procedures should be periodically re-evaluated, particularly if injection site necrosis has occurred. Anaphylaxis has been reported as a rare complication of interferon use.

Other allergic reactions have included dyspnea, bronchospasm, tongue edema, skin rash, and urticaria. The rate of flu-like symptom complex was approximately 57% in the four controlled clinical trials. The incidence decreased over time, with only 10% of patients reporting flu-like symptom complex at the end of the studies. During the therapy, monitoring of complete blood and differential white blood cell counts, platelet counts and blood chemistries, including liver function tests, are recommended at regular intervals. The most commonly reported adverse reactions are lymphopenia, injection site reaction, asthenia, flu-like symptom complex, headache and pain. The drug may also pose potential risk to pregnancy.

Market size

Interferon beta-1b has been available globally for more than 13 years and was formerly known as NVF233. The first beta interferon was marketed by Bayer-Schering for the treatment of MS under the name, Betaferon®/Betaseron®. The drug is the same medicine as Extavia. Novartis gained rights to its own branded version of this medicine in agreements with Bayer-Schering related to the acquisition of Chiron. Extavia was launched in line with an agreement of Bayer-Schering that established the A patent application for Copaxone (glatiramer acetate), a multiple sclerosis drug marketed worldwide by Israel-based Teva Pharmaceuticals Industries in India was blocked by India's Natco Pharma in March 2009.

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MS belongs to the central nervous system (CNS) disorder category and the total CNS drugs market in India reached around Rs18 billion in 2009-10. Major players in the segment are: Sun Pharmaceuticals, Torrent Pharma, Abbot India, and Lundbeck India. Other players which are making major inroads into this market are: Intas Pharmaceuticals, Micro and Sanofi-Synthelabo India, USV and Elder Pharmaceuticals.

Outlook

About 36% of Multiple Sclerosis (MS) patients are currently treated with MS drugs, & expected to increase to 56% by 2014 as new oral MS therapies are launched, which shows bright opportunity for oral drugs in multiple sclerosis market. The UK is expected to be one of the promising markets for MS treatment in the coming years. Currently, the country accounts for only 1.1% of the total MS treatment market in the world. Worldwide, MS treatment revenues are expected to exceed US\$9 billion during the second half of next decade. The prevalence and onset of MS in children and adults is expected to rise steadily. This would further drive up the market for MS treatment in the world. An increase in the number of aged people, increased life expectancy, unmet clinical needs together with advances in treatments of neurodegenerative diseases, such as Alzheimer and Parkinson disease will continue to contribute to the expansion of the global market for MS treatment. Extavia is expected to face direct competition from the later launch of additional oral pipeline disease-modifiers, which will represent tough direct competition from 2012 onwards, leading to decline in sales.

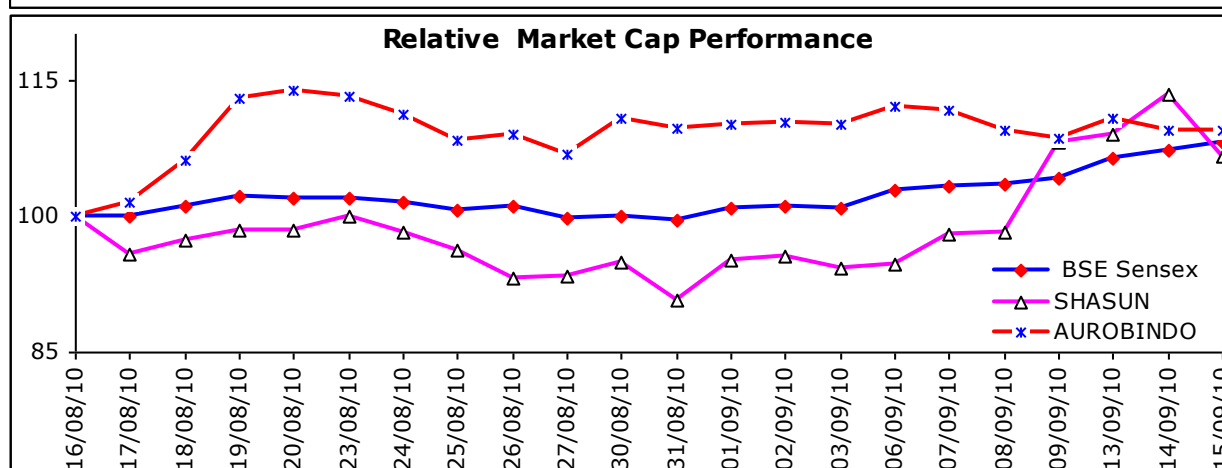
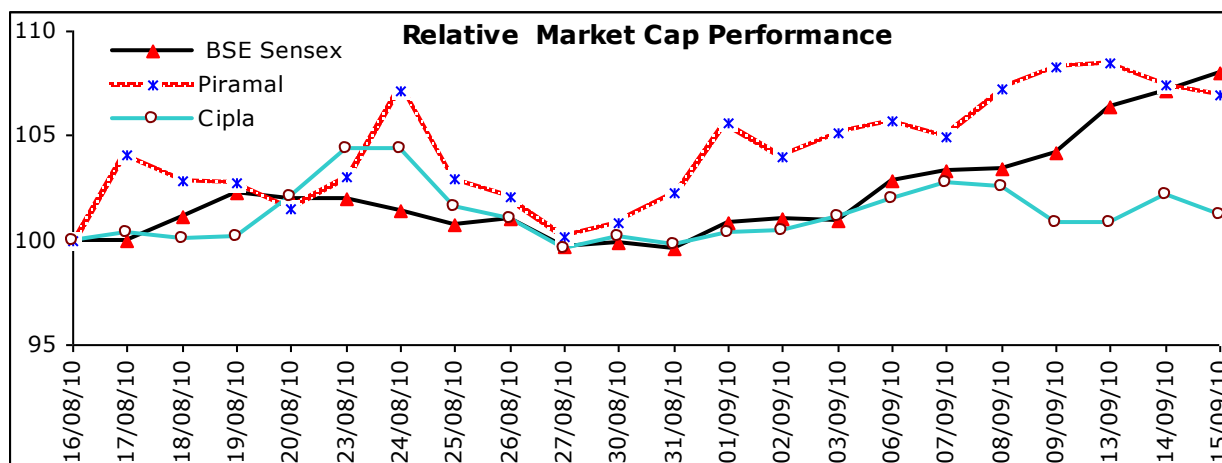
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Stock Scan



Source: BSE India; Cygnus Research;

Index	1 st Week (16-23 Aug, 2010)			2 nd Week (24-31 Aug, 2010)		
	Opening	Closing	Var(%)	Opening	Closing	Var(%)
BSE (points)	18,050.78	18,409.35	2	18,311.59	17,971.12	-1.86
Cipla	304.00	317.30	4.38	317.25	303.35	-4.38
Piramal	486.55	501.45	3.06	521.30	497.70	-4.53
SHASUN	84.25	84.30	0.06	82.70	76.35	-7.68
AUROBINDO	948.50	1074.25	13.26	1053.70	1039.60	-1.34

Index	3 rd Week (01-07 Sep 2010)			4 th Week (08-15 Sep 2010)		
	Opening	Closing	Var(%)	Opening	Closing	Var(%)
BSE (points)	18,205.87	18,645.06	2.41	18,666.71	19,502.11	4.48
Cipla	305.05	312.30	2.38	311.70	307.55	-1.33
Piramal	513.85	510.45	-0.66	521.85	520.55	-0.25
SHASUN	80.15	82.60	3.06	82.75	89.85	8.58
AUROBINDO	1044.35	1057.95	1.30	1037.00	1038.60	0.15

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Regulatory Issues

INTERNATIONAL

FDA and EPA Guidelines US

The pharma industry in the United States is required to comply with several rules in order to be sure the level of quality of the products in manufactures, the basic safety of its employees and members of the public, and the environment where it works. Many of those are issued by the Food & Drugs Agency (FDA), which is out there to give protection to the public wellness by being sure all food products and drug products used by humans are safe. Products taken care of by Food & Drugs Agency rules include drugs, biological products, medical devices, foods, cosmetics and devices that emit radiation.

U.S. Pharma Packaging Market to Grow 5.5% Annually Through 2014

Demand for pharmaceutical packaging in the US (including Puerto Rico) will increase 5.5% annually to US\$18.4 billion in 2014. Upgraded regulations and standards address such issues as barrier protection, infection control, patient drug compliance, drug dispensing errors, and drug diversion and counterfeiting will underlie growth. An increased focus on these issues will boost demand for high value-added containers and accessories, including enhanced barrier plastic bottles, calendar and wallet blister packaging, prefillable syringes and inhalers, track and trace and authentication labels, and unit dose pouches.

NATIONAL

The Department of Pharmaceuticals (DoP) is going to introduce the new plan called Pharmaceuticals Credit Linked Capital Subsidy Technology Upgradation Scheme for compliance to GLP by the Small and medium Enterprises. The essence of the scheme is to extend capital subsidy on loan/institutional finance availed by the SMEs for such technology upgradation. Under the scheme, the Centre will give financial assistance by giving 25% upfront capital subsidy to pharma SMEs on loan/institutional finance availed by them from identified primary lending institutions like scheduled banks and financial institutions for new equipment and machineries required for compliance to Schedule L-1, limited to the project cost of upto Rs.10mn and thus the total capital subsidy limit will be Rs.2.5mn per SME.

Industry asks govt to extend CLCSS scheme to upgrade units under GLP

The Department of Pharmaceuticals is seriously contemplating to roll back its much publicized Credit Linked Capital Subsidy Scheme (CLCSS) for Schedule M due to the extremely poor response from the industry the industry has asked the government to extend the jinxed scheme to the Good Laboratory Practices (GLP) which becomes mandatory from November 2010. The DoP to continue the financial support to the small pharma units by continuing the CLCSS scheme for the technical upgradation of units under Schedule M, the industry has asked the DoP to upgrading required under the Schedule L-1 for GLP should be included in the CLCSS scheme. This necessary as the small units are in dire need of financial support from the government for upgrading their units as per the GLP norms set by the union health ministry.

NPPA to launch consumer oriented campaign on availability of low cost drugs

The National Pharmaceutical Pricing Authority (NPPA) has finalised the details of a nationwide consumer-oriented mass media campaign about the drug pricing and the availability of low-cost unbranded drugs. The campaign is likely to be launched very soon as the approval for the same had been given and other details including the budgets had been finalised in consultation with the Department of Consumer Affairs. The campaign, which is the key part of the scheme 'building robust and responsive statistical system for NPPA', was the scheme to get in-principle approval from the Planning Commission under the current Five Year Plan, though the department of pharmaceuticals submitted five new schemes for NPPA.

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CII sponsored study calls for health, pharma sectors under one ministry for effective control

While slamming the current pro-industry economic policies at the cost of people's health, a CII-sponsored study has called for sprucing up the existing criteria for price control and suggested bringing all activities related to health and pharma sector under one ministry. The balance existed between industrial and health policy has taken a back seat, risking health security in the country. In its present form, the DPCO is as ineffective as it is inadequate in its coverage. There is urgent need to spruce up the existing criteria for price control. The present practice of using monopoly and market dominance measures should be replaced with the criteria of 'essentiality' of drugs. This would have maximum spill over effect on the entire therapeutic category, and is likely to prevent the present trend of circumventing price controls through non-standard combinations. The study assumes significance as CII represents the industry including the pharma and healthcare sector with large number of companies under the fold.

IDMA seeks exemption from octroi duty on bulk drugs in Maharashtra

Indian Drug Manufacturers Association (IDMA) has submitted a memorandum demanding exemption of octroi duty on bulk drugs in the state. The letter states the high rate of octroi duty on bulk drugs in Maharashtra especially Mumbai by the BMC is forcing many pharma companies to shut their units and shift them to other states. The letter submitted, points out that Maharashtra is the state charging octroi duty on various goods, with BMC imposing octroi duty between 5.55 to 7%. At present the medicines are under price control imposed by the central government, however there is no provision for additional charges like octroi duty.

Health Ministry asks State government to adopt Clinical Establishment Bill

The Union health ministry has asked the state governments to adopt the recently-passed Clinical Establishment Bill for a comprehensive database of the health infrastructure could be made and the sector can be further streamlined. Health Minister of the States to increase the allocation for the public health and take initiate stern steps to contain spurious drugs in the markets.

UP govt issues order to police to file FIR against cos marketing substandard drugs

The industry is battling with the Union health ministry for curtailing the powers of drug authorities under the amended Spurious Drugs Act, the Uttar Pradesh government has directed the state police department to initiate criminal proceedings under Indian Penal Code against the drug companies are found to be marketing substandard drugs. The UP chief minister's directive has alarmed the industry as it will have a serious adverse impact on the genuine drug manufacturers due to the directive, the police have been asked to file First Information Reports (FIRs) against the drug manufacturers who are

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Upcoming Events

1.	Event	PHARMTECH
	Date	Nov 23-26, 2010
	Venue	All-Russian Exhibition Center (V.V.C), Moscow, Russia.
	Highlights	This is a unique exhibition in Russia and the CIS exclusively dedicated to pharmaceutical production: substances, raw materials, production machinery, packaging, turn-key projects, clinical research and laboratory equipment.
	Contact Details	ITE Group Plc105, Salusbury Road, London, United Kingdom Tel:+(44)-(207)-5965000; Fax:+(44)-(207)-75965111;
2.	Event	Late Phase Drug Development World
	Date	Nov 30 – Dec 03, 2010
	Venue	TBA, London, United Kingdom.
	Highlights	Late Phase Drug Development World is where people come to look for advice, guidance and support to the key challenges they face. Late Stage Drug Development World will be one of the largest gatherings of pharmaceutical and biotech professionals in Europe. Clinical trials, Clinical research, Post marketing will be targeting Pharmaceutical, Biotechnology, Contract Research industry.
	Contact Details	Terrapinn Pte, Wren House, 43 Hatton Garden, London, UK. Tel:+(44)-(20)-70921000; Fax:+(44)-(20)-72421548;
3.	Event	P-Mec India
	Date	Dec 01-03, 2010
	Venue	Bombay Exhibition Centre(BEC), Mumbai, Maharashtra, India
	Highlights	It is the exhibition for the supplier of quality equipment and machinery for pharmaceutical manufacturing industry. The event will provide the opportunity to showcase their latest accomplishments in pharmaceutical machinery and equipment. It will offer complete coverage of all developments in the pharmaceutical word.
	Contact Details	UBM India Pvt. Ltd. A-615, Sagar Tech Plaza, Saki Naka Junction, Mumbai, India. Tel:+(91)-(22)-66122600; Fax:+(91)-(22)-66122626;
4.	Event	Biotech Showcase
	Date	Jan 10-12, 2011
	Venue	San Francisco Wyndham Hotel, San Francisco, USA.
	Highlights	Biotech Showcase provides private and public life science companies the opportunity to present to an audience of investors and business development executives.
	Contact Details	E.B.D. Group, Inc.2032 Corte del Nogal, Suite, Carlsbad, United States Of America. Tel:+(1)-(760)-9300500; Fax:+(1)-(760)-9300520;
5.	Event	Bio Business
	Date	Jan 19-21, 2011
	Venue	London, United Kingdom.
	Highlights	BioBusiness 2011 showcased deals and experts from leading pharma such as GLAXOSMITHKLINE, MERCK, BAYER SCHERING, and ASTRAZENECA. With generics threatening pipelines and M&A at every scale high on industry agendas, delegates left with the contacts they needed to ensure essential business relationships and deals which will deliver success in 2011.
	Contact Details	Worldwide Business Research535, Fifth Avenue, 8th, New York, United States Of America. Tel:+(1)-(888)-4826012; Fax:+(1)-(212)-8852798;

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6.	Event	CPhi India
	Date	Dec 01 – 03, 2010
	Venue	Bombay Exhibition Centre(BEC) Mumbai, India
	Highlights	Each year the exhibition grows larger with exhibitors and visitors conducting significant levels of business at CPhi. Two sister events, ICSE and P-MEC now run alongside CPhi, a tripartite of events that is considered the must attend for any organisation within the pharma manufacturing community.
	Contact Details	UBM India Pvt. Ltd. ; Sagar Tech Plaza A, 615-617 6th Floor, Andheri Kurla Road Saki Naka Junction, Andheri East, Mumbai, India. Tel: 66122648; Fax: 66122626;
7.	Event	International Contract Services Expo-India
	Date	Dec 01 – 03, 2010.
	Venue	Bombay Exhibition Centre(BEC) Mumbai, India.
	Highlights	It is the only truly global exhibition where you can meet, mix, mingle, and do business with worldwide pharmaceutical outsourcing customers, potential clients, decision makers and journalists.
	Contact Details	UBM India Pvt. Ltd, Sagar Tech Plaza A, 615-617 6th Floor, Andheri Kurla Road Saki Naka Junction, Andheri East, Mumbai, India. Tel:+(91)-(22)-66122648; Fax:+(91)-(22)-66122626;
8.	Event	P-Mec India
	Date	Dec 01 – 03, 2010.
	Venue	Bombay Exhibition Centre(BEC) Mumbai, India.
	Highlights	It will provide the opportunity to showcase their latest accomplishments in pharmaceutical machinery and equipment. It will be held alongside the ICSE and CPhi events, offering complete coverage of all developments in the pharmaceutical world.
	Contact Details	UBM India Pvt. Ltd., Sagar Tech Plaza A, 615-617 6th Floor, Andheri Kurla Road Saki Naka Junction, Andheri East, Mumbai, India. Tel:+(91)-(22)-66122648; Fax:+(91)-(22)-66122626;
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