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In Focus: “Vitamin Market in India – An Overview”

Introduction

As the world population continues to increase, demand for food will experience a dramatic growth. Changing demographics and the rising standard of living in developing countries will shape the eating habits of the world. Consumption of protein-rich foods, particularly meat, rises when disposable incomes increase. Expanding elderly population and rising levels of health awareness among consumers are other factors fuelling the demand. Driven by the GRAS (Generally Recognised as Safe) status of vitamins, food fortification market is on an upswing. The antioxidant and other beneficial properties of vitamins are bolstering the demand in the cosmetics industry.

What Are Vitamins?

Vitamins are a group of substances essential for normal cell function, growth and development. Vitamins are the nutrients that perform myriad functions like binding tissues, making cells strong, fighting infections and making bones strong. Vitamin supplement is a food supplement or nutrition supplement that supplies the essential vitamins to the body.

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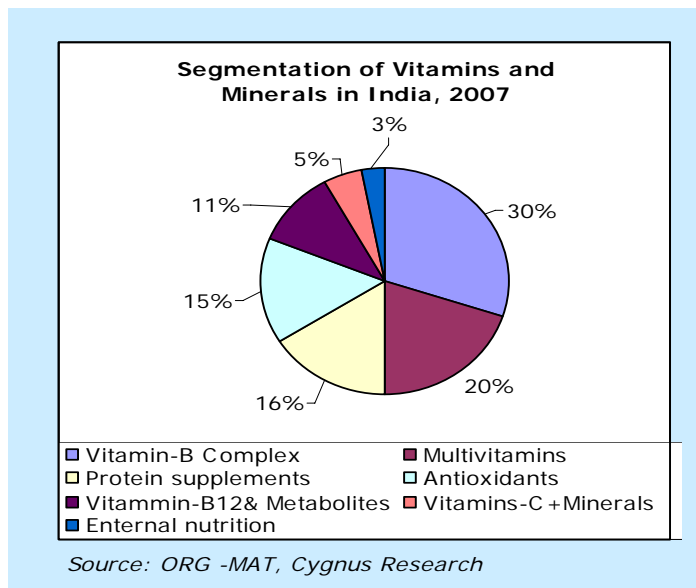
Global Market

The US, Europe, and Asia Pacific collectively accounted for more than 80% of the global vitamins market. According to a report by Global Industry Analysts, Europe is the largest market, estimated at USD967m in 2007. The world vitamin market is projected to reach USD3.2 billion by 2010. Asia-Pacific holds enormous growth potential, and is projected to be the fastest growing regional market (2000-2010). Vitamin E represents the leading segment, capturing over 30% of the market. According to the MAT figures of December 2007 released by ORG-IMS, Himalaya Drugs' Liv-52 and Pfizer's Becosules are among the top ten brands with market share of 0.38% and 0.32% respectively.

Major global players: The major players include Adisseo, Archer Daniels Midland Co, BASF AG, Boehringer Ingelheim Consumer Health Care, Cargill Inc, Cognis Corp., DSM Nutritional Products, Daiichi Pharmaceuticals, Degussa AG, Jiangsu Jiangshan Pharmaceutical Co, Ltd, and Kuraray Company.

Indian Market

Vitamins and mineral supplements market comprises Vitamin-B complex, Multivitamins, Antioxidants, Protein Supplements, enteral nutrition, Vitamin-B12 & Metabolites and Vitamin-C with minerals (See chart). Vitamin-B complex held the major market share, valued at INR2.25 billion in 2007. Multivitamins held the next major share and was valued at INR1.5 billion. Protein Supplements



was the third major segment, valued at INR1.2 billion, followed by anti-oxidants, valued at INR1.12 billion. The anti-oxidants market is booming with products like fish oils (omega 3), Alpha lipoic acid and CO Q 10. Although Vitamin-B12 & Metabolites occupied fifth place in segmental share (INR0.82 billion), it has grown drastically over the year mainly because of its health benefits like formation of RBC cells, maintenance of CNS, synthesis of amino acids and metabolism of fat,

carbohydrate and proteins. Vitamin-C with minerals and Enteral nutrition were valued at INR0.37 billion and INR0.22 billion respectively.

Major Indian players: The major Indian players include Nicholas Piramal, Maa Formulations Private Limited, Chemie Pharma, Haffkine Biopharma, Indopharma, Alembic Chemical Works, Solvay Pharma and Minova Life Sciences.

Growth Drivers

The major growth drivers for the vitamins market comprise the following:

- **Changing lifestyle**

Growth in Indian economy has been influencing and bringing a drastic change in the lifestyle of the Indian population, mainly in the urban region. A major area of concern is the changing dietary habits. Fast-food culture is becoming a part of the daily life. The high-fat, high-cholesterol diet is making people vulnerable to lifestyle diseases. According to World Health Organization (WHO), India is expected to have 57m diabetics in 2011. Increase in the incidence of lifestyle diseases indicates a potential market for vitamin supplements.

- **Rise in spending power**

Working population of India is expected to reach 64.2% of the total population by FY2021, according to the projections by the National Commission of Population, India. This will imply higher income levels of people and their spending on healthcare products. Vitamin supplements are generally consumed in addition to the normal diet and as such are not part of the core spending (on essential commodities). The spending on health supplements increases only when there is a rise in the disposable income of the people.

- **Awareness of preventive medicine**

At present, all major transnational and large Indian pharmaceutical companies have ventured into vitamin supplementary products. Preventive care is the mantra of the modern medical world. Awareness and focus on preventive therapy has increased the consumption of vitamins, minerals and nutraceuticals. Consumers are becoming health conscious and are realising the need for dietary supplements to help them cope with the fast-changing pace of life, which has increased the risk of diabetes, cholesterol, heart ailments, arthritis and so on.

- **Increase in diseases caused by malnutrition and over-nutrition**

A growing number of developing countries, such as India and the Philippines, have to shoulder the double burden of malnutrition and over-nutrition. Under-nutrition, especially among children, causes considerable number of deaths year after year. On the other hand, health problems related to over-

nutrition include overweight, obesity, diabetes, high blood pressure and diet-related chronic diseases. Vitamin supplements certainly have a significant role to play in both the cases.

- **Increasing medical costs**

The cost of curative care has been escalating with advancement in technology. Multi-specialty and super-specialty healthcare services come at exorbitant price. With the increase in the awareness of preventive care, the demand for nutraceutical products and supplements is increasing, more so because these products cost far lesser than the curative services. That most of the major transnational and Indian pharmaceutical companies have ventured into these segments is no surprise.

Outlook

Protein nutrients and vitamins, functional food ingredients like lutein, lycopene, omega-3 fatty acids, and probiotics and sterol esters, have high growth potential in the future. The vitamin supplements industry, positioned somewhere between the food and pharmaceutical sectors, presents an interesting investment opportunity because the industry is characterised by low regulatory barriers and rising consumer demand in the domestic market.



News Briefs

INTERNATIONAL

AMERICAS

USA: Emergent BioSolutions to acquire Protein Sciences for Phase III recombinant flu vaccine

Emergent BioSolutions Inc and Protein Sciences Corporation (PSC) announced that the two companies have entered into an asset purchase agreement under which Emergent will acquire PSC's ongoing operations, including FluBlok, a Phase III recombinant influenza vaccine candidate, and certain other assets. This agreement achieves a key component of Emergent's stated strategy for growth through acquisition of late-stage product candidates.

USA: Alnylam Pharma signs RNAi drug development deal with Japan's Takeda

Alnylam Pharmaceuticals Inc announced a research partnership with Japan's Takeda Pharmaceutical Co Ltd potentially worth more than USD1 billion. Besides its deals with Roche and Takeda, Alnylam also has partnerships with Novartis, Biogen Idec and the National Institutes of Health. Alnylam is among more than a half-dozen biotechnology firms developing RNAi treatments, which involve interfering with messenger-carrying RNA that can trigger disease by delivering genetic information to cells. The technology is designed to ensure a drug reaches its intended target while leaving healthy cells unharmed, unlike blunt approaches such as chemotherapy.

USA: PsychoGenics and Roche enter agreement to neuropsychiatric disorders treatment

PsychoGenics Inc and Roche have entered into a drug discovery and development agreement in which they combine their complementary strengths and expertise to identify a new generation of treatments for neuropsychiatric disorders. The agreement provides that Roche will provide drug candidates and PsychoGenics will evaluate these candidates, using its proprietary drug discovery technologies, for the treatment of neuropsychiatric disorders. Either one has the option to exclusively develop any drug candidate emerging from this collaboration, with the non-developing party receiving milestones and royalties commensurate with the stage of development

USA: Studies link lead to adult crime, brain damage

Researchers reported that exposure to lead in early childhood or in the womb can cause permanent brain damage that may even cause criminal behaviour. Studies showed that people with high levels of lead in childhood grew up with blocks of missing brain cells_ and they also were far more likely to be arrested for crimes, especially violent crimes. Researchers from University of Cincinnati College of Medicine showed how high lead levels affect the risk of being arrested in adulthood. After controlling the factors including maternal IQ, maternal arrest rates, parenting style and socioeconomic factors, they concluded that prenatal and childhood lead concentrations in the blood predicted likelihood of adult arrest.

USA: Prenatal fish intake benefits kid's brains

Researchers of Harvard Medical School in Boston said that recommendations for fish consumption during pregnancy should take into account the nutritional benefits of fish as well as the potential harms from mercury exposure. They said that fish are also the chief dietary source of omega-3 fatty acids, substances key to early brain development. Their finding that benefit of fish intake is strengthened with adjustment for mercury levels suggests that if mercury contamination were not

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present, the cognitive benefits of fish would be greater. They further said that maternal consumption of fish lower in mercury and reduced environmental mercury contamination would allow for stronger benefits of fish intake.

USA: Stronger-than-ever generic threat forces big pharma to be creative

The market for prescription generic drugs has evolved into a formidable competitive threat to branded pharmaceuticals. Driven by the large number of blockbuster drugs that have come off patent, including Prozac, Cipro and Rebetol, the market grew at a compound annual rate of 12.6%, reaching USD36.18 billion in 2007. Using increased revenues generated from generic versions of a growing number of topselling branded drugs, generic companies are exploring new drug targets, including specialty generics, generics with a distinction, generic biologics and proprietary molecules. Generic drug makers are also becoming more aggressive, challenging brand patents.

USA: Juvaris BioTherapeutics initiates Phase 1 clinical trial of JVRS-100 Adjuvanted Seasonal Influenza Vaccine

Juvaris BioTherapeutics, Inc., a biotechnology company developing therapeutics and adjuvanted vaccines for infectious diseases and cancer, announced the initiation of a Phase 1 clinical trial of its lead compound, JVRS-100. The trial will compare the safety, tolerability and immunogenicity of the JVRS-100 adjuvant co-administered with a commercial influenza vaccine compared to vaccine alone. Manufacturers of influenza vaccines are actively pursuing adjuvanted vaccines in order to improve efficacy and reduce vaccine dosage requirements due to supply constraints.

USA: Provectus Pharmaceuticals Inc begins Phase II clinical trial for atopic dermatitis

Provectus Pharmaceuticals Inc has begun Phase II clinical testing of PH-10, the company's topical drug for dermatology, for the treatment of atopic dermatitis, a chronic skin condition that includes some forms of eczema. In the study, subjects will apply PH-10 daily for upto four weeks to their skin areas affected by atopic dermatitis. Response will be observed weekly throughout this treatment phase, and for one month after the end of this period. The daily application of PH-10 in this study will also provide information relevant for treatment of other dermatologic conditions, such as psoriasis and infectious diseases of the skin, including antibiotic resistant staphylococcus aureus (MRSA), which is a growing public health concern.

Europe:

Denmark: Santaris Pharma begins human clinical testing

Santaris Pharma, the Danish biopharmaceutical company, announced that it has commenced a Phase I human volunteer trial of the world's first microRNA medicine to be tested in man - SPC3649. The study is being conducted and it will include a maximum of 48 healthy male volunteers. The company also announced that the first cohort of healthy volunteers in the study have completed treatment satisfactorily. SPC3649 is being developed by Santaris Pharma as a potential new approach to the treatment for Hepatitis C infection.

UK: Study shows benefit of statins before heart surgery

A review of clinical trial data suggested that cancer patients should perhaps avoid taking antioxidant supplements, because they may diminish the effectiveness of chemotherapy and radiation treatment. Results from the largest of the three trials suggested that antioxidant therapy reduced overall survival. However, there was evidence indicating that one antioxidant, amifostine, can protect certain healthy tissues from radiation damage without increasing resistance in cancerous tissue. Researchers conclude that some intriguing studies have benefit of adjunctive antioxidant treatments in cancer patients; the totality of the available evidence is equivocal at best with serious concerns about the potential for harm.

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France: NicOx completes patient enrollment in third naproxcinod pivotal phase III studies

NicOx S.A announced the completion of patient enrollment in the third pivotal phase III clinical trial for naproxcinod in patients with osteoarthritis of the hip. The objective of this study is to assess naproxcinod's efficacy in relieving the signs and symptoms of osteoarthritis of the hip and provide additional safety data, including further information on naproxcinod's blood pressure profile in comparison to another anti-inflammatory medication. Results from this study are expected in fourth quarter of 2008 and NicOx projects the filing of a New Drug Application in mid-2009.

UK: Novartis MS drug Extavia gains approval in EU

Swiss drugmaker Novartis announced that the European Commission has approved its multiple sclerosis drug Extavia for the treatment of early and relapsing forms of multiple sclerosis (MS). The multinational pharmaceutical group plans to launch Extavia in the US and Europe in the first half of 2009. The approval of Extavia will be able to offer the MS community a current standard of care while preparing for the introduction of innovative therapies such as FTY720. Multiple sclerosis, the chronic autoimmune disease, affects some 350,000 people in the US annually and more than 2m worldwide. The disease is more common among women than men and occurs most commonly in young adults.

EU approves its first pre-pandemic H5N1 vaccine

An H5N1 influenza vaccine made by the British pharmaceutical company GlaxoSmithKline (GSK) has become the first pre-pandemic vaccine to be licensed by the European Union (EU), the company announced. The European Medicines Agency has approved the adjuvanted vaccine, called Prepandrix, for marketing in all 27 EU countries. Researchers analysed that pre-pandemic vaccines, based on existing H5N1 strains, will offer some protection against an emerging pandemic strain of H5N1 until a specific pandemic vaccine can be developed and produced, a process expected to take 4 to 6 months. The vaccine offers European governments the opportunity to protect their populations in advance or at the outset of a declared influenza pandemic. The product is licensed for adults aged 18 to 60. The company said it has already sold supplies of its vaccine to the United States, Switzerland, and Finland.

Israeli team developing MS drug revolution

The team including doctoral student Shaher Duchi and Professor Haim Ovadia will be presenting their nasal drug delivery method at the Biomed Israel Conference 2008. Researchers stated that carrier they developed contains particles mere hundreds of nanometres in size that are found in biological membranes. These particles open a path for the drug to penetrate the nasal mucous membranes, when once they reach the brain. Today, multiple sclerosis drugs are delivered by injection. Aside from sparing patients a jab, nasal delivery could also expedite the drug's effect, which could be a huge advantage in delivery of drugs such as painkillers, sleep agents, and medications to treat serious diseases, such as Parkinson's, that impair functioning.

Israel: Teva announces approval of Generic Sarafem(R) Pulvules(R)

Teva Pharmaceutical Industries Ltd announced that the US Food and Drug Administration has granted final approval for the company's Abbreviated New Drug Application (ANDA) for Fluoxetine Capsules USP, 10mg and 20mg. Shipment of the product will begin immediately. As the first company to file an ANDA containing a paragraph IV certification for this product, Teva has been awarded a 180-day period of marketing exclusivity.

Middle East

Uganda: Pharmacies under investigation over fake malaria drugs

Health authorities have started countrywide investigations of all pharmacies over reported fake malaria drugs on the market. The aim is to establish authenticity of media reports in Uganda that a recent study by US scientists indicated that fake malaria medication was on sale in Rwanda. The drugs allegedly tested by researchers in these countries were Amodiaquine known as Camaquin, Artesunate. Regardless of fake malaria drug claims, Rwanda was ranked first by the World Health Organisation (WHO) this year among African countries doing well in the fight against Malaria.

Asia Pacific

Japanese major Konica Minolta healthcare unit ordered to pay ¥1.2billion for evading taxes

Major precision instrument maker Konica Minolta Holdings Inc and several of its subsidiaries have been ordered by tax authorities to pay back taxes on about ¥1.8 billion in income concealed over a two-year period through March 2007. The Tokyo Regional Taxation Bureau also found that the company failed to declare more than ¥200m in undeclared income, including cases of accounting errors. Consequently, it ordered the group to pay about ¥1.2 billion in back taxes, including tax arrears and fines. The subsidiary argued that the ¥700m had been paid as settlement costs to its agents who had taken over the China operations. However, the tax authorities decreed that the expenditures included compensation for lost jobs and possible bribes to government officials.

China: AMAG Pharmaceuticals, Inc and 3SBio, Inc announce strategic partnership

AMAG Pharmaceuticals, Inc and 3SBio, Inc, a leading Chinese biotechnology company announced the signing of a development and commercialisation agreement for ferumoxytol, an intravenous iron replacement therapeutic agent being developed to treat iron deficiency anaemia in chronic kidney disease patients. This is an exciting first step towards expanding the potential use of ferumoxytol outside the United States.

National News

India set for starting Pharm.D course, health ministry gives green signal

Union health ministry has at last given the green signal for the introduction of Pharm.D course in the pharmacy colleges in the country. A notification in this regard has been issued by the health ministry setting criteria for starting this course in the pharmacy colleges. Major prerequisites for starting the Pharm.D course included proper teaching and building infrastructure, tie-up with any 300-bedded hospital or own hospital and prior permission from the Pharmacy Council of India (PCI). Plus 2 students with science as main subject are eligible to join this course which will open up new vistas for the students as the course will have validity all over the world including advanced countries like US, UK, etc. For the students who have already completed B.Pharm course can join the Pharm.D (post baccalaureate) course. The duration of the Pharm.D course will be for 6 academic years (5 years of study and 1 year internship/residency). In the one year internship, a student is exposed to actual pharmacy practice/clinical pharmacy services and acquires skill under supervision so that he/she may become capable of functioning independently. Institutions running B.Pharm programme approved under section 12 of the Pharmacy Act, 1948 will only be permitted to run Pharm.D programme. Pharm.D (Post Baccalaureate) programme will be permitted only in those Institutions which are running Pharm.D programme.

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Anna University offers PG certificate course in clinical trial management

The Bio-informatics and Clinical Research Group of the AU-KBC Research Centre of Anna University, Chennai (K BChandrasekhar Research Centre) is offering an exclusive Post Graduate Certificate Course in Clinical Trial Management (CTM) from June this year at the University's MIT Chromepet Campus. According to the information received from the institute, the Research Centre is starting this course to meet the acute shortage of trained and skilled manpower to work as Clinical Research Associates (CRAs) for the conduct of clinical trials as per international standards. Students with MBBS, BIM, BHMS, BDS, B. Pharm and Degree in Life Sciences like Biotechnology and Paramedical branches will be eligible to seek admission in the course. The Research Centre has designed the Course Curriculum and is engaging doctors and scientists from Medical Colleges, Hospitals, CROs, Pharma companies, Research Institutions and Universities as specialist faculty members to teach the course. On successful completion of the course, the students will be able to find employment as Clinical Trial Associates, Clinical Research Coordinators in leading Pharma companies and CRO firms, Support staff for Investigators, Hospitals, Surveillance staff for sponsors, Bio-Statistical Services to various clients involved with clinical trials, Regulatory and Drug Control Agencies, Training faculty, etc.

India: GVK BIO enters into drug discovery pact with Wyeth Pharmaceuticals

GVK BIO announced that it has entered into a research agreement with Wyeth Pharmaceuticals, a division of Wyeth, to discover drug candidates focused on pre-defined discovery targets. GVK BIO will utilise in-house capabilities in Discovery Chemistry, Informatics, Biology and ADME to advance this program. The company will be responsible for identifying drug candidates, which will be transferred to Wyeth to advance these compounds towards clinical studies. Under the agreement, GVK BIO will receive an initial payment and will be eligible for success-based milestone payments. This agreement further validates India's capability to do innovative research along with leading pharmaceutical and biotech companies.

India: Intas Biopharma to sell lung cancer drug Gefitinib

Intas Biopharmaceuticals is launching lung cancer drug Gefitinib in India although it will sell it under Geffy brand name. This is in line with the company's sales strategy to market novel targeted therapies, for treatment of lung cancer especially non-small cell lung cancer (NSCLC). Geffy is a class of anti-cancer medications called epidermal growth factor receptor (EGFR) tyrosine kinase inhibitors. It works by blocking the action of a certain naturally occurring substance that may be needed to help cancer cells multiply. Expanding its current portfolio of lung cancer drugs, which comprises of Gemibine, Carbopa, Taxocare and Cytax, Intas is eying to grab a major market share in India.

India: Separate department for pharma sector on anvil

Union Minister of Chemicals and Fertilisers stated that, in view of the robust growth of the pharmaceutical sector, government has decided in-principle to create a separate department dedicated to the sector. The Minister said the proposed department for the pharma sector would be carved out from the existing chemical and fertiliser department, which is now also taking care of the sector. According to the officials, with India's exports, the pharmaceutical sectors too needed a separate specialised department just on the pattern of the IT industry.

India: Rising work-related health problems to cost India over USD200billion by 2015

Researchers reported that India would suffer a revenue loss of USD237 billion between 2005 and 2015 due to the rising impact of heart diseases, diabetes, cancer and chronic respiratory problems. Chronic diseases accounts for more than 60% of all deaths globally and is projected to account for 47m deaths annually in the next 25 years. More than six million people have coronary artery disease and about five million people have rheumatic heart disease. Around 2 lakh babies are born every year

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with some form of congenital cardiothoracic defect. With the aging population, degenerative diseases are also increasing. India has the largest number of diabetics in the world of about 25-30m. India is projected to have more than 37m diabetics in 2010 and more than 57m in 2025.

India: Wipro chief invested USD20m into HealthCare Global Enterprises

Wipro chief has invested USD20m in oncology player HealthCare Global Enterprises (HCG) to acquire a significant minority stake in the healthcare group. The fresh funding would help HCG in its backward integration for cancer management on a pan-India basis and make cancer treatment accessible to all segments of the society, the hospital spokesperson said. The investment from Wipro would enable the hospital to ramp up fast across various geographies besides enhancing the core research initiatives and bring cutting-edge technologies and treatment modalities.

India: Secrets of the Indian gene- first phase results of country's most ambitious science project

The Centre for Genomic Applications (ICGA), Delhi, has generated genetic information on over 4,000 genetic markers from over 1,000 biomedically important and pharmacogenetically relevant genes in reference populations encompassing diversity of populations from across the country. This collaborative project also involved the efforts of scientists and researchers drawn from six laboratories from the Council of Scientific and Industrial Research (CSIR), along with the Kolkata-based Indian Statistical Institute, and anthropologists from several institutes. The overall results of this study would help in (a) predicting of both diseases and the effectiveness of specific drugs used for their treatment and (b) designing future scientific studies to understand genetic roots of major diseases in India.

India: Dr Reddy's launches Omez Insta in sachets

Dr Reddy's Ltd announced the launch of Omez Insta in sachets, an innovative powder formulation used in the treatment of acute gastritis. Omez is the leading brand of Dr Reddy's in the gastrointestinal segment. United States Food and Drug Administration (USFDA) has also already approved the formulation. It reduces the intra gastric acidity (acid concentration in stomach) by 78% within first 30 minutes of ingestion, it added. Mint-flavoured Omez is also available in sachets that provides instant relief in acute gastritis and is also used in the treatment of critically ill patients who are using tube feeding, the company said.

India: Ipca anti-malarial formulations pre-qualified by WHO

India's largest producer of anti-malarial formulation Ipca Laboratories has been prequalified by World Health Organisation. This pre-qualification anti-malarial formulation of Amodiaquine and Artesunate coblister has made Ipca Laboratories Ltd, first company in India, to have this specific prequalification, company's spokesperson said. With this, two of Ipca's anti-malarial formulations are prequalified out of the total of five anti-malarial formulations prequalified by WHO.

India: Drug prices shooting up

Close on the heels of sharp rise in prices of most essential commodities, most essential drugs have become dearer. This is in spite of various measures such as cut in excise and customs duty on drugs and sops for pharmaceutical companies taken by the government. Ways and means have to be found to keep their prices in check. Government's appeals to the manufactures and traders to bring down prices have not had much effect. Cheaper options of popular brand names are available in the market which goes by their chemical name. One way to tackle the present crisis is to ask doctors to prescribe such cheap medicines so as to be affordable to poor patients. The government should also promote the sale of such medicines and create awareness among the public about cheaper and safe options so that they won't fall a prey to the machinations of drug companies.

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India: 650 drug companies threaten to stop production

Over 650 drug makers have asked the government to immediately increase the prices of 33 bulk drugs failing, which companies will have to stop manufacturing several medicines within a month or two. Companies say that they are already incurring losses at the current prices due to increased cost of bulk drugs and the depreciation of the rupee against dollar. Domestic drug price regulator, National Pharmaceutical Pricing Authority (NPPA) had reduced the prices of 33 bulk drug upto 10% in March on a suo-moto basis. Drug companies find their hands tied as Indian drug price laws permit companies to hike the prices of drugs up to 10% in 12 months for those drugs outside price control. The prices of the drugs are capped by NPPA. Also, as crude oil prices have touched USD135 per barrel, there is a cascading effect on all bulk drugs derived from petro chemicals.

Product Focus – Lovenox

Introduction

Lovenox is a sterile aqueous solution containing enoxaparin sodium, a low molecular weight heparin with pH of 5.5 to 7.5. The generic name of Lovenox is Enoxaparin. Like heparin, enoxaparin prevents blood clots from forming. This medication helps to keep the blood flowing smoothly by lowering the activity of clotting proteins in the blood. Enoxaparin is sometimes commonly referred to as an anticoagulant. Conditions which increase the risk of developing blood clots include certain types of surgeries (e.g. knee or hip replacement), long periods of being immobile, certain types of heart attack, and a specific type of chest pain called unstable angina. For some medical conditions, enoxaparin may be used in combination with other blood thinners. Enoxaparin works by blocking the action of two of the 12 proteins in blood whose action is necessary in order for blood to clot. The FDA has approved enoxaparin in 1993.

Storage: All enoxaparin products can be stored at room temperature, between 15 and 30°C (59-86°F).

Drug interactions:

Medications that increase the risk of bleeding can add the effects of enoxaparin and further increase the risk of bleeding that is associated with enoxaparin. Such medications include aspirin, clopidogrel (Plavix), and the nonsteroidal anti-inflammatory drugs such as ibuprofen (Motrin; Advil), naproxen (Naprosyn), diclofenac (Voltaren), and others.

Classification	
Brand Name	Lovenox
Generic Name	Enoxaparin
Therapeutic class	Anticoagulants
Manufacturer	Sanofi Aventis
<i>Source: Cygnus Research</i>	

Indications

Prevention of deep vein thrombosis, pulmonary embolism and prevention of thrombus formation during haemodialysis

Contraindications

Lumbar puncture and other invasive procedures involving CNS, Haemorrhage, and bleeding tendency.

Side Effects
Upset stomach, Black or bloody stools
Fever
Irritation or burning at site of injection
Unusual bleeding or bruising
Swollen ankles and/or feet

Side effects:

The most common side effect associated with enoxaparin is bleeding. Less commonly, enoxaparin can induce an increase in liver tests in the blood, suggesting mild damage to the liver, and a reduction in blood platelets. Mild local irritation, pain, hematoma, ecchymosis, and erythema may occur at the site of injection.

Safety profile: Enoxaparin should not be given by intramuscular injection

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Precautions

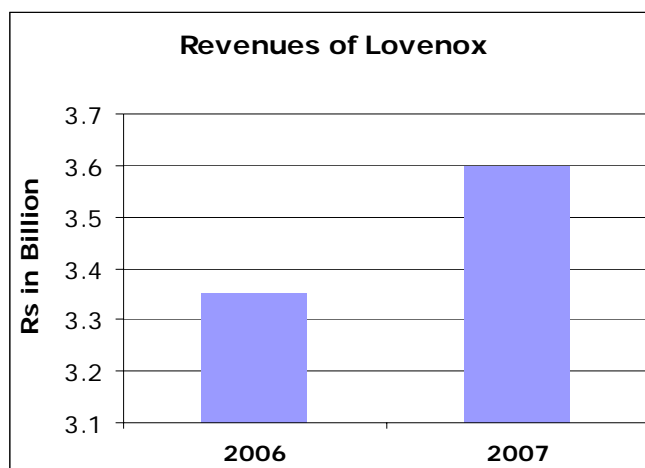
- Tell the physician and pharmacist about the allergic may be caused due to Lovenox or any other medications.
- Tell the physician and pharmacist about prescription and non-prescription medications that are presently undertaken.
- Tell the physician if you are in the medications of kidney disease, an infection in your heart, a stroke, a bleeding disorder, ulcers, or a low platelet count.
- Be sure to tell at the time of pregnancy, plan to become pregnant, or are breast-feeding

Dosage

The usual dose of enoxaparin is 30mg twice daily or 40mg once daily by subcutaneous injection. For the treatment of an existing blood clot, the usual dose is based on the weight of the patient 1/mg/kg twice daily or 1.5mg per kg once daily. The dose is dependent on the specific reason for which enoxaparin is being used. The dose of enoxaparin is reduced for patients with severe impairment of kidney function.

Revenue of Lovenox

Venous thrombosis, which is usually treated with anticoagulants, is the third most common cardiovascular disorder, affecting almost two million people each year. The most commonly prescribed low molecular weight heparin in the US and major European markets are Sanofi- Aventis and Lovenox (enoxaparin), which is derived from porcine unfractionated heparin. In 2007, sales of Lovenox increased by 7.3% from USD3.35 billion in 2006 to USD3.6 billion in 2007.



Source: Market Research.com; Cygnus Research

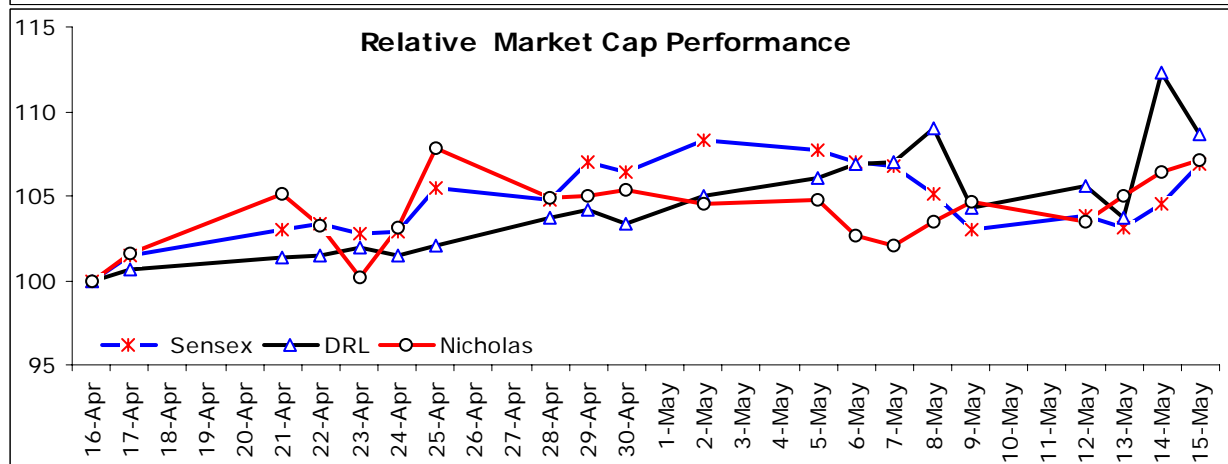
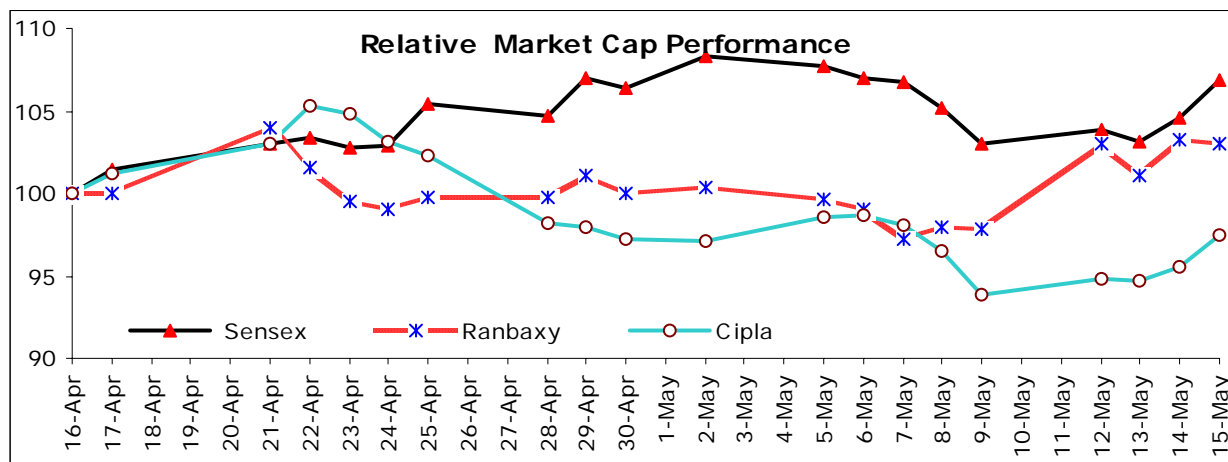
Major reasons for fast growing Enoxaparin market

- Prolonged prevention/treatment period before and after surgery
- Regional immigration boosts the medical demand
- Increased indications in oncology are developing

Outlook

Lovenox brand is the leader in the anti- thrombotics in the US, Germany, France, Italy, Spain, and United Kingdom, so many international companies are showing their interest in developing generic Enoxaparin. With its recent strategies, it wants to emerge as one of the top branded product by its net sales and market size. It is expected to register net sales of USD4.14 billion by the end of 2008-09.

Stock Scan



Source: BSE India; Cygnus Research

	April 16 - April 26	April 27 - May 03	May 04 - May 10	May 11 - May 15
BSE Sensex	Firm global markets and good results of the quarter JFM08 for many companies provided strong positive sentiments in the market. The Sensex moved up nearly 6%, during the period under consideration, to close at 17,125.98.	Firm global markets and good results continued. The Sensex moved up nearly 2.77%, during the period under consideration, to close at 17,600.12.	The markets witnessed huge selling pressure as oil & gas, realty, banking, capital goods and power stocks were under selling pressure. High inflation numbers and crude prices made the Sensex move down by 4.90%, during the period under consideration, to close at 16737.07.	Buying support from capital goods, realty, oil & gas, banking, power, technology, telecom, pharma and metal stocks made the Sensex move up nearly 3.68%, during the period under consideration, to close at 17,353.54.

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Ranbaxy	Negative results from the company made the share price decline by 0.22%.	Increase in the volume of the shares resulted in the jump in stock price from INR478.70 to INR481.45.	The stock price declined by 1.83% as the company's anti-cholesterol drug Lipitor has been rejected from US Patent and Trademark Office (USPTO) for its re-issue patent approval.	The stock price remained flat during this period.
Cipla	Positive results from the company with 2.33% in the net profit gave boost to the share prices.	Lack in demand made share prices fall by 1.02%.	The stock price closed at INR205.60 showing a decline of 4.81% as it moved in tandem with BSE Sensex.	The stock price closed at INR213.70 showing an increase of 2.84% due to the positive investors' sentiments.
DRL	The share price further increased by 2.08% as bullish sentiments prevailed in the market.	The share price increased by 1.24 as the company was planning to acquire BASF's Pharmaceutical Contract Manufacturing Business and related facility at US, leading to raise investors' confidence.	The stock price decreased by 1.57% as major players did not perform well during this period.	The stock price moved up by 2.87% as it moved in tandem with BSE Sensex.
Nicholas	The share price increased by 7.79% as the company signed an agreement to acquire CEFI Brand Groups from Khandelwal Laboratories Pvt Ltd for Cefixime and Camylofin based drugs, leading to positive sentiments to the investors.	Decreased number of shares traded resulted in the fall in the stock prices from INR345.35 to INR344.05.	Lack of demand made the share prices fall by 0.13%.	The stock price moved up by 3.51% as the company had initiated Phase I Trials with a New Molecule for Type II Diabetes in Europe, leading to raise investors' confidence

Regulatory Issues

FDA, European Medicines Agency to Consider Additional Test Results When Assessing New Drug Safety

The Food and Drug Administration (FDA) and the European Medicines Agency (EMA) worked together to allow drug companies to submit the results of seven new tests that evaluate kidney damage during animal studies of new drugs. The tests measure the levels of seven key proteins or "biomarkers" found in urine that can provide additional information about drug-induced damage to kidney cells, also known as renal toxicity. The new biomarkers are KIM-1, Albumin, Total Protein, β 2-microglobulin, Cystatin C, Clusterin, and Trefoil Factor-3. For decades, both FDA and EMA have required drug companies to submit the results of two blood tests, called blood urea nitrogen (BUN) and serum creatinine, to evaluate renal toxicity. In addition to those tests, the FDA and EMA will now consider results from the seven new tests as part of their respective drug review processes. Although a decision by the sponsor to collect information using the new tests is voluntary, if collected, it must be submitted to FDA. Development of the new biomarkers was led by the Predictive Safety Testing Consortium (PSTC), whose members include scientists from 16 pharmaceutical companies. The PSTC was organized and led by the Critical Path Institute, a nonprofit organization that works to support FDA research collaborations that improve the development of medical products.

National

NPPA turns to insulin market to reign in soaring prices

The National Pharmaceutical Pricing Authority (NPPA) has launched an exercise to reign in the domestic and international insulin manufacturers and marketers to impose a possible ceiling on the prices of this life-saving drug relied upon by over 30 million diabetics in the country. After bridling the scheduled sector tightly and stepping into the non-scheduled segment by fixing prices of many drugs to make them affordable to the common man, the national pharma price regulator is learnt to have started consultations with different groups, associations and insulin manufacturers to get a first-hand view of the pricing. Some of the companies have already made presentations to the NPPA to explain their position and justifications to the existing prices. Denmark based multinational Novo Nordisk controls about 80 per cent of the domestic insulin market while the rest of the market is shared by Eli Lilly, Biocon, Wockhardt, Cadila and US Vitamins. Thus almost 90 per cent of the market is in the hands of the multinationals. With the rise in the number of diabetics in the country, the insulin market is also growing by 20-25 per cent, according to estimates.

FDA order on patient information leaflets in Marathi annoys ayurveda industry

Perturbed by The Maharashtra Food and Drugs Administration's (FDA) recent notification asking the ayurveda industry in the state to provide patient information leaflets in Marathi language has annoyed hundreds of ayurveda units in the state as they express practical difficulties in following the FDA order. As per the FDA notification, apart from other languages, information should also be given in Marathi language in patient information leaflets so that the common people in the state who do not know any language other than Marathi can understand the information regarding the medicines.

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Karnataka drug dept cancels 750 drug licenses, suspends another 1170 during 07-08

Karnataka drugs control department has issued 3618 show cause notices for violations, 1170 licenses have been suspended and 750 licenses were cancelled for the year 2007-08. These are for the pharmacy outlets and the manufacturing units located across the State. There are around 21,745 pharmacy outlets, 158 blood banks and 241 manufacturing units in the State. For the year 2007-08, the enforcement officers of the State drugs control department have carried out 26,380 inspections on sales premises, 541 inspections on blood banks and 260 inspections on manufacturing units. Out of these 34 unlicensed dealers were detected. Around 3618 show cause notices were issued by the department for violations. In the Drug testing laboratory, a total of 3299 samples were analyzed of which 240 samples were declared as not of standard quality drugs and investigation is being carried, out.

Chemicals ministry to finalise modalities on disbursing PTUF.

The Union chemicals ministry will take a final decision on the modalities for disbursing around INR600 crore Pharmaceutical Technology Upgradation Fund (PTUF). The chemicals ministry, early this year, had assigned to NPC the task of finding some workable solution in disbursing the fund which was introduced by the government to financially assist the small scale pharma units for upgrading their facilities to meet the Schedule M norms. The NPC is in its last leg of touring different parts of the country where small scale pharma clusters are located. The NPC has already visited northern parts and is presently touring Indore before proceeding to Maharashtra.

PTUF scheme was launched by the government for the benefit of thousands of pharma SSI units spread across the country. The objective of the scheme is to assist the SSI units in technological upgradation of their manufacturing facility in compliance with the Good Manufacturing Practices (GMP) as per standards fixed by Union health ministry in Schedule M of Drugs and Cosmetics Rule, 1945. Under the scheme, the government proposes to reimburse 5 per cent point interest on the loans taken from the banks or financial institutions. SIDBI was named the nodal agency for the scheme.

Upcoming Events

1	Event	Organic Process Research & Development
	Date	June 23-26, 2008
	Venue	Montréal, Canada
	Highlights	<ul style="list-style-type: none"> ➤ Presenting important and detailed case studies ➤ Learn to design for efficiency and optimise your development objectives ➤ Discover the strategies are evolving to meet the challenges ➤ Current developments, future trends and meet and network with key people working in the chemical and pharmaceutical industries
	Contact Details	Contact: Kate Laird, Scientific Update LLP, Maycroft Place, Stone Cross, Mayfield, TN20 6EW, UK, Tel. +44 (0)1435 873062; Fax: +44 (0)1435 872734, Website: http://www.scientificupdate.co.uk E-mail: sciup@scientificupdate.co.uk
2	Event	Cardiology Update in Primary Care Medicine
	Date	Jun 23-27, 2008
	Venue	Hyatt Sarasota, Florida, USA
	Highlights	This presentation will teach both medical device therapies for such common patient complaints as CHF, HTN, Tachy and Brady arrhythmias. It will also teach the skills of ECG “first-read” and management options that are most needed in the settings of rural office and emergency rooms, as well as after-hours interpretation in any clinic or urgent care settings.
	Contact Details	Organiser, American Medical Seminars, Inc P.O. Box 49947, Sarasota, Florida Tel: 1-941-388-1766; Fax: 1-941-365-7073 Email: mail@ams4cme.com ; Web: www.ams4cme.com
3	Event	Pharma Asia
	Date	Jul 05-07, 2008
	Venue	Karachi Expo Centre, Karachi, Sindh, Pakistan
	Highlights	Pharma Asia is being organised at the most opportune time when the Government is looking forward to expand the developing industries of the Country, which have shown tremendous growth in the past few years. The exhibition would serve as a comprehensive showcase of the latest in technology, equipment and machinery as well as allied services, while providing investors with a definite outlook of the regional pharmaceutical industry.
	Contact Details	E- Commerce Gateway Pakistan Private Limited 18, C. P Berar Society, Off Amir Khusro Road, Karachi, Pakistan. Tel: +(92)-(21)-4536321; Fax: +(92)-(21)-4536330
4	Event	Critical Care Symposia 2008
	Date	Jul 01-04, 2008
	Venue	Alexander Fleming Building, Imperial College, London
	Highlights	<ul style="list-style-type: none"> • An update on the latest developments in the overall ICU management of acute organ failure • A forum to share and exchange views with leading experts within the field of renal, respiratory and cardiac medicine • An opportunity to gain a raised awareness of the impact of acute organ failure on the ICU

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	Contact Details	MA Healthcare Ltd FREEPOST SO6080, Salisbury, UK Tel: +44 (0)1722 716007; Fax: +44 (0) 1722 716926
5	Event	Pharmaceutical Portfolio & Product Life Cycle Management
	Date	July 2-3, 2008
	Venue	The Hatton, London, United Kingdom
	Highlights	<ul style="list-style-type: none"> • Strategic portfolio management and planning, pairing in-house and alliance products • Emerging markets and therapy areas, pricing analysis • Future Mapping Commercial Opportunity
	Contact Details	The Organising Secretary, Simon Curtis, The Hatton, London Email: scurtis@smi-online.co.uk
6	Event	145th Annual Convention, American Veterinary Medical Association
	Date	Jul 19-22, 2008
	Venue	New Orleans, LA, USA
	Highlights	Sectors of domestic and international business and a new educational program format in 50 minutes sessions. The program will include lectures, interactive labs, special symposia, practice management, and technology classes for: veterinarians, veterinary technicians & students, practice managers and veterinary office staff.
	Contact Details	American Veterinary Medical Association Tel: 800-248-2862; Fax: 847- 925-1329 E-mail: convention@avma.org; Web: www.avmaconvention.org
7	Event	9th Clinical Pharmacology and Therapeutics (CPT 2008)
	Date	July 27- August 1, 2008
	Venue	Quebec City Convention Centre, Canada
	Highlights	Exclusive event for clinical pharmacology, clinical pharmacy, pharmacology and toxicology and improved therapeutics to support better health outcomes.
	Contact Details	The Organising Secretary, Canadian Society for Clinical Pharmacology (CSCP) Tel: +1 (613) 993-0414; Fax: +1 (613) 993-7250 Email: cpt2008@nrc-cnrc.gc.ca; Website: www.cpt2008.org
8	Event	Drug Discovery & Development of Innovative Therapeutics
	Date	August 04-07, 2008
	Venue	World Trade Centre Boston & Seaport Hotel, USA
	Highlights	This is an ultimate goal of the pharmaceutical and biotechnology industries which is to bring innovative medicines to the marketplace. It will highlight how companies are moving from discovery to the clinic in creative ways and with less resource.
	Contact Details	The Organising Secretary, IBC, 200 Seaport Boulevard, Boston, MA 02210 Tel: 617-385-5000; Fax: 617-385-5090 Email: custserv@ibcusa.com; Website: www.drugdisc.com

9	Event	FICCI - HEAL 2008
	Date	Aug 07-08, 2008
	Venue	FICCI, New Delhi
	Highlights	FICCI endeavour, through this conglomeration of policy makers and leaders from healthcare and associated industries from India and abroad is to assess the Indian and global scenario, deliberate on the emerging opportunities, challenges and solutions to define a road map for growth of the health services sector. The aim is to arrive at workable strategies for expansion of quality healthcare provision at an affordable price from cities to towns and eventually to the villages through local and global collaboration and cooperation
	Contact Details	Shobha Mishra, Joint Director, FICCI Tel: +91-11-23722921; Fax: +91-11-23320714 Email: healthservices@ficci.com
10	Event	Zak India Chem Pharma Expo (Zak ICPE)
	Date	Aug 13-17, 2008
	Venue	Singapore Expo, Singapore.
	Highlights	Zak India Chem Pharma Expo (Zak ICPE) will showcase the Indian chemical & pharma industries, products, companies and new offerings. This event will provide an excellent platform for business to business contacts and help producers, manufacturers, importers & exporters to network with bulk buyers of chemicals in the ASEAN region
	Contact Details	ZAK Trade Fairs and Exhibitions Private Limited, 49 (Old No. 27), Veerabadran Street, Nungambakkam, Chennai, India., Tel: +(91)-(44)-28257722; Fax: +(91)-(44)-28254488
11	Event	Indonesia International Bio Pharma Expo
	Date	August 20-23, 2008
	Venue	Jakarta International Expo (JIExpo), Indonesia.
	Highlights	Indonesia International Pharma Expo is an International Exhibition on Pharmaceutical, Raw Materials, Active Ingredients, Processing Machinery, Packaging Machinery, Equipments. The manufacturers and suppliers of process plant and equipment, for this growing industry, would attend the exhibition, all under one roof.
	Contact Details	The Organizing Secretary, Krista Media Pratama PT., Krista Exhibitions, Jln.Blandongan 28 DG, Jakarta, Indonesia., Tel: +(62)-(21)-6345861; Fax: +(62)-(21)-6340140, Website: www.kristamedia.com; Email: info@kristamedia.com;