

**Year at a
Glance**

PHARMA SPECTRUM

2008

SPECIAL ISSUE

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International IPR

1. Eli Lilly Sues Aurobindo, Lupin for Patent Violation

December 5, 2008, Business Standard

US-based pharma giant Eli Lilly has filed cases against Indian drug makers Aurobindo Pharma and Lupin, alleging infringement of patent of its anti-depressant drug Cymbalta.

Filing a petition on November 24 before the US District Court for the Southern Districts of Indiana, Eli Lilly has alleged that Lupin's US subsidiary Lupin Pharmaceuticals has infringed its Cymbalta patent.

2. Sanofi-Aventis Settles Allegra Patent Suits in the US

November 28, 2008, SCRIP

Sanofi-Aventis has agreed to settle some long-standing US patent infringement suits with Barr Pharmaceuticals and Teva Pharmaceutical Industries related to Allegra (fexofenadine), granting the generics makers certain patent rights. As the two generics firms are already marketing US versions of the allergy drug, there will be some royalties for what has been sold in the past and royalties for future sales.

3. Roche Files Third Suit Against Orchid Over Best-Selling Drug

November 2, 2008, The Mint

Mumbai: Swiss drug maker F Hoffman La Roche Ltd last week filed a third lawsuit in a US court to block an application by Indian firm Orchid Chemicals and Pharmaceutical Ltd. seeking marketing approval for a generic version of Boniva, Roche's best-selling prescription drug for osteoporosis.

4. Pfizer To Pay \$894 Million To Settle Lawsuits

October 18, 2008, Financial Express

Pfizer Inc said Friday it plans to pay \$894 million to settle lawsuits alleging that its withdrawn Bextra painkiller and widely used Celebrex arthritis drug harmed U.S. patients and defrauded consumers. Pfizer said the money would be paid out under three separate tentative settlements -- including one that

resolves claims by 33 states and the District of Columbia primarily related to Bextra marketing practices.

5. Patent Expiry Concerns Dent Outlook for European Pharma

October 3, 2008, SCRIP

Europe's pharmaceutical industry is profitable, with good growth opportunities, but looming patent expiries and greater generic competition threaten its immediate prospects.

These are the main points highlighted in an "industry outlook" report from analysts at Moody's Investors Service, who evaluated the prospects for the European pharmaceutical sector over the next 12 to 18 months. Its outlook for European pharmaceutical companies is negative, owing to the challenges the sector faces. However, the industry has robust cash-flow generating ability and solid liquidity. Prospects for growth remain good as well, with remaining unmet medical needs as well as an aging population.

6. Generics? No Thanks, We're Glaxo

Posted by Jeanne Whalen - The Wall Street Journal

Others in Big Pharma may be stepping up their investment in generics, but GlaxoSmithKline's new CEO isn't going there.

"I've got no interest in the classic U.S.-style generic marketplace," he said during a recent interview in London. "It's a different kind of business. It's not just about low cost of production. It's about your aggressiveness in invalidating people's patents, it's about being first to do that. And I think it's a tough world to play in. We've got far better ways we can create value," he told the Health Blog.

7. Wyeth In Patent Row With Sandoz Over Generic Protonix IV

May 30, 2008 SCRIP

Wyeth and its partner Nycomed have filed a lawsuit against Novartis's Sandoz unit, alleging the company's application to sell a generic version of the 40 mg injectable formulation of the ulcer drug Protonix (pantoprazole sodium) that infringes a US patent covering the product. Wyeth markets the product as Protonix IV.

Regulatory

1. Novartis' Gleevec Wins US Approval

December 21, 2008, Hindu Business Line

Novartis AG said its best-selling cancer drug Gleevec won US approval to slow the recurrence of a rare gastrointestinal tumour after surgery. Gleevec is the lone post-surgical treatment cleared by the US Food and Drug Administration to delay the return of the aggressive stromal tumours, the company said in the statement on PR Newswire. The approval illustrates how the continued study of a once-novel drug throughout its product lifecycle can yield new and important uses, said Richard Pazdur, director of oncology drugs for the FDA's Center for Drug Evaluation and Research. Gleevec is used as a treatment for leukemia and gastrointestinal tumours. - Bloomberg

2. Abbott's Trilipix Gets US FDA Nod for Use in Combination with Statin for LDL Cholesterol

Wednesday, December 17, 2008, Pharmabiz, Abbott Park, Illinois

The US Food and Drug Administration (FDA) approved Abbott's Trilipix (fenofibric acid) delayed-release capsules for use along with diet to help lower triglycerides and LDL cholesterol, and to raise HDL cholesterol in patients with lipid problems.

Trilipix is the first and only fibrate to be approved for use in combination with a statin. In certain patients, treatment guidelines recommend the combination of a fibrate with a statin to further improve lipid levels. Trilipix has not been shown to prevent heart disease or heart attack.

3. 'Rosiglitazone' Removed From Diabetes Drugs

December 11, 2008, The Hindu

The debate over the use of controversial anti-diabetes drug 'rosiglitazone,' associated with heart attacks, congestive heart failure and bone fractures, is finally settled after a revision of international guidelines threw the drug out.

The American Diabetes Association and European Association for the Study of Diabetes (EASD) have removed the drug from the list of recommended second line drugs, following reports since mid last year of increased risk of heart attacks in patients using rosiglitazone. Diabetologists in the State have hurried

to welcome this move, one they say is "belated, but certainly a right step."

4. FDA Approves J&J's Analgesic Tapentadol

December 5, 2008, SCRIP

Johnson & Johnson has received US FDA approval for its analgesic tapentadol hydrochloride, an immediate-release oral tablet, for the relief of moderate - to - severe acute pain in the US, its first market.

"This approval offers healthcare professionals an additional choice for treating moderate to severe acute pain", said Dr. John Jenkins, Director of the Office of new drugs in the FDA's Center for Drug Evaluation and Research.

5. US FDA Approves Astellas' Premixed Formulation of Vaprisol

October 27, 2008, Pharmabiz, Deerfield, Illinois

Astellas Pharma US, Inc announced that the US Food and Drug Administration (FDA) has approved a new premixed formulation of Vaprisol (conivaptan hydrochloride injection) premixed in 5 per cent Dextrose.

Discovered and developed by Astellas, Vaprisol, an arginine vasopressin (AVP) receptor antagonist, is the first and only approved drug indicated for the treatment of both euvolemic and hypovolemic hyponatremia in hospitalized patients. Hyponatremia is a potentially life-threatening condition that occurs when the body's blood sodium level falls significantly below normal. Vaprisol was originally approved by the FDA in an ampule formulation for the treatment of euvolemic hyponatremia in December 2005 and hypovolemic hyponatremia in February 2007.

6. US FDA Approves Eisai's Ontak Sbla for Cutaneous T-Cell Lymphoma

October 18, 2008, Pharmabiz, Woodcliff Lake, New Jersey

Eisai Corporation of North America announced that the US Food and Drug Administration (FDA) has approved an efficacy supplemental biologics license application (sBLA) for Ontak (denileukin diftitox) solution for intravenous injection for the treatment of patients with persistent or recurrent cutaneous T-cell lymphoma (CTCL) whose malignant cells express the CD25 component of the interleukin (IL)-2 receptor (CD25+). A separate efficacy supplement that included data from patients with CTCL whose malignant cells did not test positive for the CD25

component of the IL-2 receptor received a complete response letter.

7. Lilly Gets US FDA Nod for Pemetrexed-Cisplatin Combo for Lung Cancer

October 6, 2008, Pharmabiz, Indianapolis

Eli Lilly and Company announced it received approval from the US Food and Drug Administration (FDA) for the use of Alimta (pemetrexed for injection), in combination with cisplatin, in the first-line treatment of locally-advanced and metastatic non-small cell lung cancer (NSCLC), for patients with nonsquamous histology. Alimta is not indicated for treatment of patients with squamous cell non-small cell lung cancer. NSCLC is the most common form of lung cancer, resulting in more than 180,000 new cases in the US each year.

NSCLC is defined as a group of histologies, that is, tumour types differentiated by cellular structure. Nonsquamous histology includes adenocarcinoma, large cell carcinoma and all other histologies except squamous cell carcinoma.

8. UCB's Epilepsy Drug Keppra XR Gets US FDA Nod

September 17, 2008, Brussels, Belgium

UCB announced that the US Food and Drug Administration (FDA) has approved Keppra XR (levetiracetam extended-release tablets) for use as an add-on to other antiepileptic treatments for people with partial onset seizures who are 16 years of age and older.

Keppra XR is expected to be available in US pharmacies at the end of September 2008, an UCB press release said.

The goal of therapy with antiepileptic drugs (AEDs) is freedom from seizures and minimal side effects. While many people with epilepsy are successfully treated with one or more of the currently available AEDs, a significant percentage still live with uncontrolled seizures or intolerable side effects.

9. Merck Vaccine Wins OK For Vaginal Cancer

September 14, 2008, Hindustan Business Line

U.S. health regulators have approved Merck and Co's Gardasil vaccine to protect women against rare vaginal and vulvar cancers, the Food and Drug Administration said on Friday.

The vaccine is already available in the United States to prevent cervical cancer and genital warts in girls and women ages nine to 26 years old.

Gardasil was already approved for abnormal and precancerous vaginal and vulvar lesions, but the FDA said new evidence showed it benefited related cancers as well.

10. Wyeth's Tigecycline Gets US FDA Approvable Letter

June 5, 2008, Chronicle Pharmabiz

Wyeth Pharmaceuticals, a division of Wyeth, announced that the US Food and Drug Administration (FDA) has issued an approvable letter for the first-in-class antibiotic Tygacil (tigecycline) for the treatment of adult patients with community acquired pneumonia (CAP).

11. US expands label for Bristol-Myers Squibb / Otsuka's Abilify

28th & 30th May, 2008, SCRIP

The US FDA has expanded the approved indications for Bristol-Myers Squibb / Otsuka's atypical antipsychotic Abilify (aripiprazole) to include its use as an adjunctive therapy to either lithium or valproate for the acute treatment of manic and mixed episodes associated with bipolar I disorder with or without psychotic features in adults.

New Products

1. Lilly Launches Colour Differentiation System for Humalog, Humulin U-100 Insulin Products in US

November 1, 2008, Pharmabiz, Indianapolis

Eli Lilly and Company announced the introduction of a colour differentiation system for U-100 insulin products marketed in the United States, including vials, pens and individual packaging for Humalog (insulin lispro injection [rDNA origin]) and Humulin (regular insulin human injection, USP [rDNA origin]).

2. Novo Nordisk's Flexpen Enhanced

September 19, 2008, SCRIP

Novo Nordisk has announced a number of enhancements to its FlexPen prefilled insulin injection device, which includes a simple twist mechanism to attach and detach needles. This makes it the first pen

device able to use a new generation of needles, the company says. Other changes include the need for less force to inject oneself, a single dose-setting mechanism, and a non-medical appearance. FlexPen is the most widely used prefilled insulin device in the world, the company notes.

3.Schering-Plough Launches Bridion In Europe

September 15, 2008 , Kenilworth, New Jersey - SCRIP

Schering-Plough Corporation announced that the European launch of Bridion (sugammadex) injection has begun with its introduction this week in Sweden, and that the product is expected to be available soon in the United Kingdom and Germany, with several other European markets to follow by the end of the year and in early 2009.

R&D/Clinical Trials

1.GSK Presents Positive Safety & Efficacy Results from RAISE

December 9, 2008, Pharmabiz, London

GlaxoSmithKline (GSK) presented positive safety and efficacy results from RAISE (RANdomised placebo-controlled ITP Study with Eltrombopag), a phase-III study of Promacta/Revolade (eltrombopag) in adults with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who had received one or more prior ITP therapies. Patients receiving eltrombopag were eight times more likely than those on placebo to maintain platelet counts between 50-400,000/mL during a six-month treatment period, thereby reducing patients' bleeding symptoms and their need for concomitant and rescue ITP treatments. These data were presented at the 50th Annual Meeting of the American Society of Haematology (ASH), December 6-9, 2008, in San Francisco, CA.

2.Study Shows Lipitor Better than Simvastatin in Reducing Cardiovascular Risk

December 5, 2008, Pharmabiz, New York

Pfizer announced the results of an observational study that showed patients taking Lipitor (atorvastatin calcium) had a significant 13 per cent reduction in the relative risk of experiencing a cardiovascular event compared with patients taking simvastatin (Zocor) therapy. The patients in this study did not have evident cardiovascular disease and were newly initiated on either treatment. This study

was performed in conjunction with HealthCore, WellPoint's health outcomes research subsidiary. Results of this study, from one of the largest US managed care claims databases with more than 219,000 adult patients, were published in the December issue of Mayo Clinic Proceedings.

3.Wyeth, Progenics Report Positive Results From Phase III Study of Relistor

December 1, 2008, Pharmabiz, Tarrytown, New York

Wyeth Pharmaceuticals, a division of Wyeth, and Progenics Pharmaceuticals, Inc. said their phase III clinical study investigating Relistor (methylnaltrexone bromide) subcutaneous injection to treat opioid-induced constipation (OIC) in patients with chronic, non-cancer pain achieved statistical significance for the primary and key secondary efficacy endpoints. Adverse events observed in this study were similar to those seen in prior studies of subcutaneous Relistor.

The positive outcome reported today was from the double-blind, randomised placebo-controlled portion of a phase III clinical study.

4.Boehringer Unveils R&D Entry into Type-2 Diabetes Arena

October 21, 2008, Pharmabiz, Ingelheim, Germany

Boehringer Ingelheim announced that patients and physicians may have several innovative type-2 diabetes treatment alternatives available in the coming years. At its Second International Research & Development Press Conference, Boehringer Ingelheim unveiled a pipeline of unique oral anti-diabetic compounds in phase-II and III, establishing the company in the type-2 diabetes arena.

5.Abbott's Xience V Drug Eluting Stent Demonstrates Clinical Superiority To Taxus

October 15, 2008, Pharmabiz, Washington

Data from an independent meta-analysis of Abbott's SPIRIT-II and SPIRIT-III randomized clinical trials demonstrated that the Xience V Everolimus eluting coronary stent system continues to deliver clinically significant benefits for patients compared to the Taxus paclitaxel-eluting coronary stent system out to two years.

In this meta-analysis, which included patients from the United States, Europe and Asia-Pacific, Xience V demonstrated clinical superiority to Taxus in the endpoints of target vessel failure (TVF) and major

adverse cardiac events (MACE) at two years. Xience V also demonstrated significantly lower clinical events rates than Taxus in the key efficacy (target lesion revascularization) and safety (cardiac death or heart attack) components of MACE at two years. The results are being presented by Gregg W Stone, principal investigator of the SPIRIT-III trial, during the Cardiovascular Research Foundation's 20th annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium.

6. Advanced Life, Wyeth Sign Pact For Cethromycin In Asia Pacific Region

October 6, 2008, Pharmabiz, Chicago

Advanced Life Sciences Holdings, Inc and Wyeth Pharmaceuticals, a division of Wyeth have signed a development and commercialization agreement for cethromycin in the Asia Pacific region excluding Japan.

Cethromycin is a novel once-a-day oral antibiotic for the treatment of community respiratory tract infections. Advanced Life Sciences will retain exclusive rights to cethromycin in the rest of the world, including North America and Europe and excluding Japan. Advanced Life Sciences separately announced the submission of a new drug application (NDA) to the US FDA for cethromycin for the indication of mild-to-moderate community acquired pneumonia (CAP).

7. Roche Invests 215 Mn Swiss Francs For Diagnostics Facility At Penzberg

October 3, 2008, Pharmabiz, Basel

Roche is investing 215 million Swiss francs (136 million euros) in research, development and production at its site in Penzberg, near Munich. The money will be used to construct a multi-purpose building for Roche Diagnostics.

8. Bayer Files Recombinant Thrombin In Europe

September 5, 2008, SCRIP

Bayer Schering Pharma has filed for EU approval of Recothrom, its recombinant human thrombin (thrombin alfa) product. Recothrom is administered topically to surgical wounds as a spray or with a surgical sponge, and activates the final steps of the coagulation cascade to stop bleeding. The product was approved in the US in January (Scrip Online, January 18th, 2008) and is marketed there as Recothrom Thrombin topical (Recombination) by ZymoGenetics, its developer.

9. Boehringer Ingelheim, Ablynx Extend Alzheimer's Disease Research Pact

August 25, 2008 Ghent, Belgium

Ablynx, a pioneer in the discovery and development of nanobodies, a novel class of antibody derived therapeutic proteins, announced that the Alzheimer's disease collaboration with Boehringer Ingelheim was proceeding well and therefore the research funding has been extended for another year.

In January 2007 Boehringer Ingelheim and Ablynx announced that they had entered into a \$265 million worldwide research and licensing agreement to discover and develop new therapies for Alzheimer's disease using Ablynx's Nanobodies, a novel class of therapeutic proteins. The deal also included a joint research programme with Ablynx scientists. Boehringer Ingelheim will be solely responsible for the development, manufacture and commercialization of any products resulting from the collaboration. As part of the collaboration, Ablynx received an upfront fee and will receive development and commercial milestones as well as undisclosed royalties based on net sales.

Mergers & Acquisitions/ Collaborations

1. GSK to Acquire BMS Pakistan for \$36.5 Million

December 24, 2008, Pharmabiz, London

GlaxoSmithKline (GSK) has entered into a definitive agreement through which GSK will acquire Bristol-Myers Squibb Pakistan (Private) Ltd (BMSP) and certain associated trademarks for approximately \$36.5 million (£24.6 million).

2. Wyeth Pharma Acquires UK Based Thiakis

Saturday, December 20, 2008, Pharmabiz, Collegeville, Pennsylvania

Wyeth Pharmaceuticals, a division of Wyeth, announced that it has acquired Thiakis Limited, a privately held biotechnology company based in the United Kingdom. Thiakis' lead product candidate, TKS1225, is being studied for the treatment of medical obesity and other co-morbidities. TKS1225 and related compounds are

synthetic versions of the natural gastrointestinal peptide oxyntomodulin.

3. Merck Serono Acquires Manufacturing Rights & Facility for Stimuvax from Oncothyreon

Saturday, December 20, 2008, Pharmabiz, Darmstadt

Merck Serono, a division of Merck KGaA, announced that it has modified the license from Oncothyreon to include the right to manufacture Stimuvax (BLP25 liposome vaccine) and also has purchased current inventory and certain assets used for the manufacture of Stimuvax from Oncothyreon Inc. for a total amount of approximately US\$13 million. Merck Serono already held the clinical development and commercialization rights for Stimuvax under license from Oncothyreon.

4. Roche Acquires Memory

December 5, 2008, SCRIP

Roche is to acquire Memory Pharmaceuticals, a US based developer of CNS drug candidates, for around \$ 50 million in a definitive merger agreement. Roche will begin a tender offer to acquire all outstanding Memory shares for \$0.61 per share in cash, a significant premium when compared with the \$0.15 closing price on November 24th.

5. J&J to Buy Mentor Corp for \$1 Billion

December 2, 2008, The Economic Times

Johnson & Johnson (J&J), the world's largest healthcare company, will acquire the breast implant maker Mentor Corp for \$1.07 billion in cash.

6. Daiichi Sankyo Sets Up Subsidiary In Ireland

December 1, 2008, Pharmabiz, Dublin

Daiichi Sankyo, the third-largest Japanese pharmaceutical group and one of the world's leading research-driven pharmaceutical companies, has established its own subsidiary in Ireland. As part of this effort, 14 employees from the cardiometabolic sales force at Merck Serono Ltd are being transferred to Daiichi Sankyo effective immediately.

7. Abbott Sells Spine Business To Zimmer

September 12, 2008, SCRIP

Abbott Laboratories is to sell its Spine business for \$ 360 million to the US-based spine speciality company Zimmer. The business was formed by Abbott's acquisitions of Spinal Concepts for \$ 60 million in 2003 and Spine Next for \$ 200 million in 2004.

8. Sanofi-Aventis Completes Symbion Acquisition

September 5, 2008, SCRIP

Sanofi-Aventis has completed the A\$560 million (\$481 million) acquisition of Australia's Symbion Consumer from Primary Health Centre. The move is expected to help the French company expand its nutraceuticals business in the Asia-Pacific region. Symbion Consumer, part of Symbion Health, manufactures, markets and distributes nutraceuticals and other over-the-counter products throughout Australia and New Zealand.

9. Lilly Completes SGX Pharma Acquisition

August 22, 2008 Indianapolis

Eli Lilly and Company announced that it has completed the acquisition of SGX Pharmaceuticals, Inc, a San Diego-based biotechnology company focused on drug discovery and development in the area of oncology. The completion of the deal followed Special Stockholders Meeting, in which a majority of SGX stockholders voted in favour of the merger agreement with Lilly.

10. Roche Snaps Up More Biotech Firms

July 25, 2008, SCRIP

Roche has announced two more biotech acquisitions, of Mirus Bio and Arius Research, although both are valued at substantially less than the \$ 44 billion that it has just bid for the remainder of Genentech (*Scrip Online*, July 21st, 2008).

Pricing

1. UK Industry Agrees Flexible Five-Year Price Plan

November 28, 2008, SCRIP

The UK pharmaceutical industry and the government have reached agreement on a new five-year pharmaceutical price regulation scheme (PPRS) that

revises rather than rewrites the system that has governed drug pricing in the UK for 50 years. When the government announced last year that it was scrapping the PPRS, many in industry feared a radical overhaul, but the version mostly finalised this week retains the principal elements of the original scheme.

2.MNC Drug Cos Mull Differential Pricing

November 11, 2008 Mint

Faced with less-than-expected sales, foreign firms plan to offer drugs at lower prices for some groups; move also aimed at thwarting competition from generic suppliers

The foreign drug makers plan to offer these medicines at different tiers of prices for government supply, patient access programmes, hospitals in rural areas and non-profit organizations, said an official with the Organisation of Pharmaceutical Producers of India (OPPI), an industry body that chiefly represents foreign drug firms present in India. The discussions are at an early stage and the strategy may vary for individual companies, he said.

3.UK Drug To Be Slashed By 5%

June 20, 2008, SCRIP

The UK drugs bill could be cut by up to 5% through a new pharmaceutical price regulation scheme, the UK government and the Association of the British Pharmaceutical Industry have announced. The scheme includes a 2% basic price cut and an additional 3% price cut via other measures.

New Appointments

IFPMA Appoints Alicia Greenidge as New Director General

Geneva 30 May 2008

The international Federation of Pharmaceutical Manufacturers & Associations IFPMA is pleased to announce the appointment of Alicia Greenidge as its New Director General. She will take office on 2nd June 2008 & will succeed Dr Harvey Bale, who is retiring after almost eleven years in the position.

Domestic

IPR

1.HC Orders Review of Roche's Drug Patent

December 3, 2008, Business Standard

First time, an Indian court revisits a patent office order. In a ruling that can have far-reaching implications on the way medicine patents are granted in the country, the Madras High Court today called for re-examination of a patent granted to Swiss drug maker F Hoffman-La Roche's valgancyclovir, marketed under the brand name Valcyte in India.

2.IPA Urges DCGI To Exclude Infringement Of Patent Rights From New Definition Of Counterfeit Drugs

September 15, 2008, Pharmabiz

The Indian Pharmaceutical Alliance (IPA) has urged the DCGI to exclude infringement of patent rights, parallel importation of original goods from a third country where they have been sold by the appropriate right-holder and the diversion of supplies of authorized items from the scope and definition of counterfeit medicines.

3.Linking Patent Status With Marketing Approval Of Drugs May Not Harm Industry

July 2, 2008, Pharmabiz

Over 95 per cent of the drugs being produced in India are off-patent and will not be affected by the product patent regime. The proposed linking of patent status of drugs with marketing approvals will not have any bearing on the other existing drugs too, according to the assessment made by the authorities,

4.Pfizer & Ranbaxy Settle Lipitor Patent Litigation Worldwide

June 18, 2008, Pharmabiz

Pfizer Inc, has entered into an agreement with generics manufacturer Ranbaxy Laboratories Ltd. of India and certain of its affiliates to settle substantially all their patent litigation worldwide involving Lipitor, the world's most-prescribed cholesterol-lowering medicine.

Under the terms of the agreement, Ranbaxy will have a license to sell generic versions of Lipitor and Caduet in the US effective November 30, 2011.

5. Cipla Files Pre-Grant Opposition For 50 Drugs

June 2008 - CHEMICAL INDUSTRY DIGEST

Drugs major Cipla has filed pre-grant opposition for over 50 drugs in various patent offices in India. If the pre-grant oppositions are successful, it will pave the way for introduction of cheap drugs in the country

6. DCGI Preparing Document To Bring In System For Patent Linkage

May 24, 2008, Pharmabiz

The Drugs Controller General of India's (DCGI's) office is preparing a document in a bid to lay down a system to follow while granting marketing approvals. The step is to address the issue of patent linkage between the drug regulatory authority and the Indian patent office.

Once prepared, the document will be made available for the industry for discussion and the authority will ensure protection of interests of the pharmaceutical industry, according to Dr Surinder Singh, DCGI. The document is expected to address the hot issues related to the non linkage between the DCGI's office and the patent office, which has much concerned the foreign innovator companies and the Indian generic companies.

7. Delhi HC Passes Interim Order In Favour Of Cipla In Tarceva Case

March 20, 2008, Pharmabiz

Cipla has won the first round of the battle to continue marketing of the disputed anti-cancer drug Tarceva (Erlotinib) in the country after the Delhi High Court rejected an injunction plea by Swiss drug major Roche who holds the Indian patent right to the drug.

However, Justice Ravinder Bhat specified that it was an interim order and asked Cipla to keep separate record of the sale of its generic anti-cancer drug (Erlolcip), which is priced at one-third of the price of original Roche's version (Erlotinib). The court rejected the appeal in public interest, considering the difference in the prices of the two drugs. The court has given four weeks time to Roche to respond.

8. Chemicals Ministry Revives Plan To Control Prices Of Patented Drugs

January 2, 2008, Pharmabiz

The government effort to bring the drugs patented abroad under mandatory price negotiations prior to their marketing in the country has got a fresh lease of life with the reconstituted body holding its first meeting recently.

Regulatory

1. Govt Collects 31000 Samples in Nationwide Survey of Spurious Drugs

December 26, 2008, Pharmabiz

Even as the controversy still persisted over the quantum of spurious drugs in the country and the attempt to redefine the counterfeit drugs in line with the WHO instructions, the health ministry has started its much-publicized and much-delayed survey of collecting samples to ascertain the exact percentage of spurious drugs in the country.

2. USFDA set to open India Office in Jan

December 22, 2008, The Mint

The US food and drug administration, or FDA, will open an office in New Delhi in January after the Union government approved the proposal.

"The government of India has approved the placement of an FDA acting country director in India and FDA has a staff member currently assigned and in-country," Christopher Kelly, press officer at FDA, told *Mint* by email. "We anticipate increasing our staff and formalizing the offices in the coming weeks."

3. No Probe into Doctor-Pharma Nexus: Ramadoss

December 17, 2008, The Economic Times

In a rather weak response to TOI's expose on how pharma companies were plying doctors with expensive freebies in return for prescribing medicines produced by them, Union health minister A Ramadoss said doctors should follow their personal code of conduct and refrain from 'accepting perks or bribes'

Ramadoss told TOI that the Medical Council of India and State Medical Councils must ensure that its voluntary ethical code of conduct was strictly followed by the doctors. The code limits gifts to modest proportions.

4. Clinical Establishments Bill to expand purview to cover all healthcare bodies

December 1, 2008, Pharmabiz

The Government will redraft the Clinical Establishments (Registration and Regulation) Bill 2007 to expand its purview the entire gamut of healthcare establishments including public health institutions, laboratory and diagnostic services, R&D facilities taking up clinical trials on patients and all systems of medicine for mandatory registration.

5. Pharma Dept Plans to Introduce Quality Mark for Generic Drugs

September 30, 2008, Pharmabiz

The Department of Pharmaceuticals is planning to make another attempt to introduce quality mark on the lines of the ISI or the Agmark approvals for generic drugs manufactured and sold in the country, for ensuring quality of medicines and helping the consumers to identify it.

Though a similar proposal was made by the chemicals department some time back after a working group of the Planning Commission suggested it, the health ministry shot down the move saying that the government cannot introduce separate or different quality marks.

6. Rajya Sabha Passes Bill on Spurious Drugs with Severe Penalties on Oct 21

October 24, 2008, Business Standard

Rajya Sabha has passed the Drugs and Cosmetics (amendment) Bill 2005, seeking to enhance the punishment from five years in prison to 10 years and raising fine from Rs 10,000 to Rs 10 lakh for manufacturers of spurious and adulterated drugs.

The bill, incorporating the amendments suggested by the Parliamentary standing committee, however did not provide for death penalty as a punishment for those engaged in the manufacture and sale of spurious drugs which are likely to cause death and grievous injury to patients.

7. OPPI Seeks New Product Status For Biosimilars In India

May 12, 2008, Pharmabiz

The Organisation of Pharmaceutical Producers of India (OPPI) has sought the Union Health Ministry to consider classifying all biosimilar products as new products

enforcing all the procedures needed for the approval of a new product in the market.

The OPPI in its recent representation to the Union Health Ministry pointed out that the biosimilars vary from the innovators due to their nature and complexity of manufacturing process, though the sameness of molecular structure in chemistry based generic medicines is very much defined. Any alteration to the manufacturing process of biological drugs may result in a completely different product and it should not be considered as a similar product to the original biopharmaceutical product from the innovator company.

The organization has also offered its support for capacity building exercise in Indian Patent Office, as the authority has over one lakh patent applications pending for consideration. "From 2005 to 2008, about 10 pharmaceutical products have been granted patent by the Indian Patent Office. As we understand, there are only around 40 patent examiners in the patent office and the work is moving at a snail's pace. We have expressed our willingness to collaborate with the Department of Industrial Policy and Promotion towards capacity building and sharing best practices with the patent office," added Ray.

8. Indian Pharmacopoeia 2007 Released In Chennai

January 22, 2008, Pharmabiz

After its release in Delhi, last month, the Indian Pharmacopoeia 2007 which has many new features to match its counterparts in developed countries and encompassing over 1500 monographs was formally launched in Chennai on Jan 21 through an interactive session with the stake-holders. The new monographs would be made effective from 1st April 2008.

Under the Chairmanship of Debashish Panda, joint secretary, union ministry of health and family welfare, Dr. GN Singh, member secretary-cum-scientific director of Indian Pharmaceutical Commission conducted the interactive session with the stake-holders. Shanthi Gunasekaran, Incharge-CDSCO (south zone), R.S. Anbu Elango, Director of Drugs Control, Tamilnadu, Dr. Murugaesan, incharge-CDTL, Chennai, other senior officials and industry representatives attended the session.

New Products

1. MSD Pharma to Launch Drugs at India-Specific Prices

December 5, 2008, The Economic Times

MSD Pharmaceuticals, a wholly-owned subsidiary of Merck & Co, plans to launch its branded drugs in the domestic market at lower rates compared to the prices in the developed countries, a top official of the company said.

"From the very beginning, we are working on launching our drugs in the domestic market at India specific prices and in every six months we will be launching a new drug," MSD Pharmaceuticals India Managing Director Naveen A Rao told PTI.

2. Novo Nordisk Launches New Flexpen With Less Injection Force, Improved Safety Features

October 10, 2008, Pharmabiz

Novo Nordisk has now introduced the latest version of the FlexPen at the European Association for the Study of Diabetes (EASD) annual meet.

This next generation of FlexPen requires 30 per cent less force when injecting, when compared with SoloSTAR 2,3,4. Like the current version of FlexPen, the next generation of FlexPen provides superior dose accuracy in comparison to SoloSTAR 2,5,6. In addition, the new device provides a range of new design features aimed at improving safety and simplicity for people with diabetes.

3. Merck Launches HPV Vaccine Gardasil in India

October 14, 2008, Pharmabiz

MSD Pharmaceuticals (India), the local affiliate of Merck & Co, has launched Gardasil (quadrivalent human papillomavirus recombinant vaccine), as India's first vaccine to help prevent cervical cancer.

The vaccine, first launched globally in 2006 and approved in more than 100 countries worldwide, is touted to be the only vaccine that helps protect against 4 types (type 6,11,16,18) of HPV.

4. MSD Launches New Vaccine for Cervical Cancer

October 16, 2008, Hindu Business Line

MSD Pharmaceuticals, a wholly- owned subsidiary of Merck & Co, plans to launch vaccines for various diseases including chicken pox, hepatitis A, rotavirus and zoster in the next two-three years. The company launched its cervical cancer vaccine under the brand 'GARDASIL'.

R&D / Clinical Trials

1. Pharma Bodies Come Out with Disclosure Code for Clinical Trials

December 4, 2008, Business Standard

Even as drug regulators the world over are becoming more stringent in scrutinising clinical trials, associations of large pharmaceutical companies in the United States, Europe and Japan have come out with a uniform disclosure code for the clinical trials sponsored by them.

The disclosed information will include a short description of the clinical trials in layman's terminology, its phase, its purpose, condition of disease, location of trial and contact details of the investigators.

2. EMEA's Paediatric Trial Regulation May Push Up Number of Trials in Young Population in India

December 1, 2008, Pharmabiz

With the European Medicines Agency (EMA) announcing its Paediatric Regulations, many developing countries including India will now see an increase in the number of clinical trials carried out in children, according to a section of clinical research organizations (CROs) and hospitals in Karnataka.

3. No Clinical Trial For Drugs Developed Outside India

October 16, 2008, The Economic Times

The health ministry will put on hold its plans to grant permissions to multinational pharma firms for conducting phase I clinical trials of molecules developed outside India until it finalises guidelines for effective monitoring and supervision in the country.

4. Relax Export Norms to Tap Global Clinical R&D Market'

September 28, 2008, Hindu Business line

There is a need to relax the norms pertaining to export of body fluids and test samples to cash in on the huge opportunity in contract research and clinical trials,

according to **Mr Tapan Ray, Director-General, Organisation of Pharmaceutical Producers of India.**

"Pharma industry in India is over-regulated and there is a need for giving licences for export of body fluids and test samples. We have been requesting the Drug Controller General of India for this," Mr Ray said on the sidelines of healthcare and pharma conclave at Indian School of Business here on Saturday.

5. Health Ministry To Give Permission For Phase I Trials In India Soon

July 16, 2008, Pharmabiz

The Union health ministry may soon grant permission to conduct phase I clinical trials in the country for the molecules developed outside India. So far, phase I trials are approved by the government for such drugs which are discovered in India only.

According to sources, after dilly dallying on the issue for some time the health ministry has given its green signal for the conducting phase I clinical trials for molecules developed outside India. Several clinical research organisations have been approaching the government for approval for phase I trials for some years.

Mergers & Acquisitions / Collaborations

1. Finally, Ranbaxy becomes part of Daiichi Sankyo

October 24, 2008, Business Standard

Japanese drug major Daiichi Sankyo today completed its acquisition of a 52.5 per cent equity stake in India's Ranbaxy Laboratories through off-market and stock exchange transactions.

With this, India's largest drug-maker, which inspired many of the country's pharmaceutical companies to go global in the past decade, has become a subsidiary of the Tokyo-headquartered firm. The deal, announced this June, is worth Rs 19,850 crore and gives Daiichi access to Ranbaxy's expertise in generic drug-making.

2. Valuations of M&A in pharma sector down by 50% in first 5 months

June 28, 2008, Pharmabiz

Notwithstanding the large number of announcements, the total disclosed valuations of mergers and acquisitions in the pharmaceutical sector during the first five months of the current year came down by more than 50 per cent, according to an analysis by ASSOCHAM.

The study on 'M&A Trends in Jan-May 2008', said that the number of deals has gone up from 8 in the corresponding period of 2007 to 17 this year, but the valuations went down by half. The total value was around 940 million dollars during January-May this year against two billion dollar in August-December 2007.

Pricing

1. NPPA Sets Up 2nd CIFG for Information Facilitation, Grievances Centre in Mumbai

Saturday, December 20, 2008, Pharmabiz

The drug regulator National Pharmaceutical Pricing Authority (NPPA) has established the centre for information facilitation and grievances (CIFG) in Mumbai. Known as NPPA-CIFG, the new centre would act as consumer grievance redressal forum. Secretary in the department of pharmaceuticals Ashok Kumar formally inaugurated the centre. NPPA chairman AK Banerjee was also present in the inaugural function.

2. Govt Plans to Bring 354 Drugs Under Control List

December 19, 2008, Press Trust of India

The government proposes to bring 354 medicines under control list to bring down the prices of essential drugs, Chemicals and Fertilisers Minister Ramvilas Paswan told the Lok Sabha today.

Replying to supplementaries during the Question Hour, he said the government has asked state-run hospitals to use generic drugs for treatment of patients in a bid to make healthcare more accessible to the poor.

3. NPPA Turns Down Industry Demand For Unilateral Increase Of Drug Prices

June 16, 2008, Pharmabiz

The National Pharmaceutical Pricing Authority (NPPA) has literally turned down the pharma industry's demand for a suo moto increase in prices of medicines. The industry's demand for the upward revision in the drug prices was based mainly on two reasons: the steady depreciation of rupee against US dollar and the rising raw material costs.

According to NPPA sources, the national pharma pricing regulator has informed the industry in no uncertain terms that the authority cannot take any suo motu decision to increase the prices of medicines. However, the authority has said that while it cannot give a general relief to the drug industry, but it can consider individual price revision applications from the pharma companies.

4.NPPA Revises Guidelines Making 10 % Price Hike Only From April 07 January 21, 2008, Pharmabiz

The National Pharmaceutical Pricing Authority (NPPA) has revised the guidelines for monitoring of prices of non-scheduled formulations, making the 10 per cent ceiling in prices effective only from April 1, 2007, instead of January 2007.

The guidelines have been revised in pursuance of Resolution No. 33/7/97- PI.I, dated 29.08.1997 issued as per the provisions of the Drugs (Prices Control) Order, 1995 read with Essential Commodities Act, 1955, said an official release.

New Appointments

Price Control is Necessary in Drug Market, Dr. A.K. Banerjee, Chairman, NPPA

November 25, 2008, The Economic Times

The government has tried to keep the prices of many essential drugs under check through the Drug (Prices Control) Order (DPCO), 1995. The National Pharmaceutical Pricing Authority (NPPA) is responsible for ensuring compliance. However, drug companies have often managed to flout the norms through innovative means. Dr A K Banerjee, who took over as the chairman of the NPPA recently, discusses the issue with Sushmi Dey. Excerpts from an interview.

Drug companies often allege that the NPPA's periodicity of price revision in the case of bulk drugs is such that it does not match the fluctuations in the prices of inputs. How would you react to it?

1.Dr VM Katoch Appointed Director General Of ICMR

November 22, 2008, Pharmabiz

Dr VM Katoch, MD, has taken over dual charge as the first secretary, Department of Health Research (DHR), government of India and also the director general, Indian

Council of Medical Research (ICMR). Dr Katoch has been appointed to hold the charge of secretary, DHR and DG, ICMR for the next five years until February, 2013.

2.NPPA New Appointment - Right to Information Act, 2005 (CIPO) & (CAPIO) November 18, 2008, NPPA

Right to information Act, 2005 - Designating of Central Public Information Officer (CPIO) and Central Assistant Public Information Officer (CAPIO) for National Pharmaceutical Pricing Authority (NPPA).

Insupersession of Office Order of even number dated 08.04.2008 and pursuance of the provisions of Section 5(1) and Section 19 of the Right of Information Act, 2005, the NPPA hereby designates the following Officers as CPIO & CAPIO for the purpose of the said Act:-

1. Shri K.K. Jain, Director (Enforcement) as Central Public Information Officer (CPIO)
2. Shri S.C. Goel, Section Officer as Central Assistant Public Information Officer (CAPIO)

3.NPPA Chief Takes Over As Pharma Secy Govt Sets Up New Pharma Department, Ashok Kumar To Head July 7, 2008, Pharmabiz

In an effort to handle the growing pharmaceutical pricing and regulation needs, the government has notified the formation of a new department, the Department of Pharmaceuticals, under the Ministry of Chemicals and Fertilisers in the beginning of July.

The new department will be responsible for all matters relating to National Pharmaceutical Pricing Authority (NPPA) including related functions of price control and monitoring. Ashok Kumar, chairman of the NPPA took over the secretary in the new Department of Pharmaceuticals.

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Mint, March 29, 2008

[Pharma MNCs ask DCGI to liaison with patent offices](#)

Financial Express, March 19, 2008