New monographs included in USP-NF with effect from 1st February 2011
* Amlodipine Besylate Tablets (posted 28-Jan-2011; official 01-Feb-2011)
* Carvedilol (posted 28-Jan-2011; official 01-Feb-2011)
* Fentanyl (POSTPONEMENT) (posted 28-Jan-2011; official 01-Feb-2011)
* Fluticasone Propionate Nasal Spray (posted 28-Jan-2011; official 01-Feb-2011)
* Mefloquine Hydrochloride (posted 28-Jan-2011; official 01-Feb-2011)
* Mycophenolate Mofetil Tablets (posted 28-Jan-2011; official 01-Feb-2011)

Bayer and Zydus Cadila sign Joint Venture agreement to strengthen pharmaceutical business in India

Bayer HealthCare and the Indian company Zydus Cadila signed an agreement on 28th January 2011 in Mumbai, India, to form the Joint Venture Company Bayer Zydus Pharma. With this newly established marketing and sales enterprise, Bayer aims to enhance its presence in the fast growing pharmaceutical market in India. Each party will hold 50 percent of the shares of Bayer Zydus Pharma, and be equally represented on its management board.

For Bayer HealthCare the formation of Bayer Zydus Pharma is a crucial element of the company’s strategy to build a stronger presence in the emerging markets. "With this step, we aim to significantly accelerate our capabilities to better serve the fast growing
Indian market. We believe that the Joint Venture between Bayer HealthCare and Zydus Cadila will provide a win-win situation for both partners," said Dr. Jörg Reinhardt, CEO of Bayer HealthCare AG. "We expect to leverage on the strengths of the Joint Venture such as the optimized product portfolio and the distribution capabilities to enhance the launch of new products and the sales of existing brands."

Both partners will bring into Bayer Zydus Pharma a complementary product portfolio and specialized sales forces in women’s healthcare, diagnostic imaging, and general medicines as well as oncology. The new company, headquartered in Mumbai, India, will furthermore combine Zydus Cadila's strong Indian marketing and sales expertise as well as excellent distribution and industry network with Bayer HealthCare's expertise in successfully commercializing novel products and sophisticated administration and sales processes according to international standards. In total some 600 employees, coming from both Bayer HealthCare as well as from Zydus Cadila, will join Bayer Zydus Pharma.

Bayer Zydus Pharma will operate in key segments of the Indian pharma market with a focus on: women's healthcare, diagnostic imaging, cardiovascular diseases, anti-diabetic treatments, and oncology. Bayer Zydus Pharma's future product portfolio will not only include in-licensed and originator brands, but also patented pharmaceuticals from Bayer HealthCare's pipeline. The combined portfolio will encompass among others such popular brands as Glucobay®, Xarelto®, Nexavar® and Yaz/Yasmin® from Bayer HealthCare as well as products currently marketed by Zydus Cadila such as Euglim®, Progynova® and Ultravist®.

Source: pharmaalive.com

Pharmaceutical companies see a tough year ahead

The Wall Street Journal reports that pharmaceutical companies believe that 2011 will be a challenging year for the industry. AstraZeneca, Novartis and other pharmaceutical companies face the loss of patent protection on key drugs. In addition, drug makers are bracing for price pressures from government austerity measures and the recently passed healthcare law.

NSAID usage common, but Little Knowledge of side effects

The Los Angeles Times "Booster Shots" blog reported that a study published in the February issue of the British Journal of Sports Medicine finds that non-steroidal anti-inflammatory drug use "among some tri-athletes may be high, although users might not always be aware of the drugs' side effects." Of 327 athletes, "59.9% of those surveyed said they used the drugs in the past three months." Among 196 of the athletes, "63.8% knew about potential gastrointestinal complications, but only 31.1% were aware of possible renal complications, 20.9% about kidney failure and 26% about stomach bleeding."

Maryland lawmakers consider barring gifts to Physicians

Maryland lawmakers are again considering legislation to bar gifts from companies to health care providers in the wake of allegations that a cardiologist was "indirectly influenced" to perform unnecessary stent procedures by Abbott Laboratories. Vermont and Massachusetts have recently enacted similar laws, considered the most restrictive in the nation, that significantly limit the items sales representatives can offer to physicians, prohibiting trinkets, trips and most meals. They also require public disclosure of certain financial transactions.

Illinois town worried about impact of Abbott layoffs


Lake County, Illinois officials are bracing for the loss of hundreds of jobs at Abbott Laboratories’ sprawling campus near North Chicago. Abbott announced yesterday that it would eliminate 1,900 U.S. jobs of its estimated 90,000 employees worldwide. About 1,000 will be in Illinois, and the majority will come from Lake County, where the company is the second-largest employer, with about 15,700 workers, according to statistics.

**Pioglitazone: potential bladder cancer**
United States of America — The Food and Drug Administration (FDA) is reviewing data from an ongoing, ten-year epidemiological study designed to evaluate whether pioglitazone (Actos®), is associated with an increased risk of bladder cancer. Findings from studies in animals and humans suggest this is a potential safety risk that needs further study. Pioglitazone is used in adults with type 2 diabetes mellitus.

Bladder cancer is estimated to occur in 20 per 100,000 persons per year in the United States and is thought to be higher in diabetics. FDA has not concluded that pioglitazone increases the risk of bladder cancer. The Agency is reviewing information related to the safety concern and will update the public when additional information is available.


**Zoledronic acid solution: renal dysfunction**
Canada — The manufacturer of zoledronic acid 5 mg/100 mL solution for intravenous infusion Aclasta®) has informed healthcare professionals of important safety information. As of 30 April 2010, 265 spontaneous reports of renal impairment have been received following administration of Aclasta®, corresponding to a reporting rate of approximately 20 cases per 100,000 patient-years of exposure. The following precautions should be taken to minimize the risk of renal adverse reactions.

- Zoledronic acid should not be used in patients with severe renal impairment.
- Zoledronic acid should be used with caution when concomitantly used with other drugs that could impact renal function.
- Creatinine clearance should be calculated before each treatment followed by periodic monitoring of serum creatinine in patients with risk factors. Transient increase in serum creatinine may be greater in patients with underlying impaired renal function.
- Patients should be appropriately hydrated, especially elderly patients and those receiving diuretic therapy.
- A single dose of Aclasta® should not exceed 5 mg and the duration of infusion should be no less than 15 minutes.


**Sitaxentan: worldwide withdrawal**
Australia — The Therapeutic Goods Administration (TGA) has advised that the supply of the prescription medicine sitaxentan (Thelin®) will be suspended. The company that supplies the medicine has announced that it will withdraw Thelin® from the market globally.

Sitaxentan is a prescription-only medicine used to treat pulmonary hypertension. Patients currently taking sitaxentan should contact their physician as soon as possible to organize the supply of a different medicine but should not cease their use of sitaxentan until they have been assessed and switched to another medication. This action has been taken in response to a review of safety data in clinical trials that showed patients were at risk of acute liver failure that in some cases was not reversible.

The TGA has received 10 adverse event reports of abnormal liver function in Australian patients receiving sitaxentan.

*Reference:* TGA Safety Alert, 10 December 2010 at
Scientists discover substance which may help improve memory

The Wall Street Journal reports that, according to research published in the journal Nature, scientists claim to have discovered a substance, called IGF-II that may help improve their memory, at least in rats. When researchers blocked IGF-II, the rodents could not retain memories and forgot what they had learned. Notably, the study findings suggest that declarative memory (that is, the ability to remember things, places, and facts) can be improved. In patients with Alzheimer's and other kinds of dementia, for example, declarative memory is severely affected. The scientists called for further study of IGF-II and said their findings indicate yet another possible future target for treating dementia in humans.

FDA approves OTC Fexofenadine sales

The Wall Street Journal reports Sanofi-Aventis announced that its allergy drug Allegra (fexofenadine) will be available without a prescription beginning in March. The AP reports, Sanofi-Aventis "said the FDA approved over-the-counter sales of Allegra. The approval includes Allegra 12- and 24-hour tablets, liquid and tablet medications for ages 12 and older, children's Allegra 12-hour tablets for children as young as 6, and Allegra-D 12- and 24-hour allergy and congestion extended release tablets for ages 12 and older."

The Boston Globe "Daily Dose" blog reported Allegra "joins Claritin [loratadine] as an over-the-counter antihistamine that's not associated with drowsiness and, if priced similarly, will be 75 cents to a dollar per pill. Zyrtec [cetirizine], a bit more expensive, is also a newer antihistamine that's gone over-the-counter, but it does cause drowsiness." Both drugs have "much cheaper" OTC generic equivalents, and, "no doubt, Allegra will, too, once its patent expires."

Forthcoming Events:

IPA President’s National Seminar on Regulatory Challenges - Global Pharmaceutical Market
5th March, 2011, Hotel Grand Kakatiya, Hyderabad, India

Programme:
8.30 – 9.30 a.m. - Registration
9.30 – 9.45 a.m. - Welcome Address - Dr. C. Gopalakrishna Murty, President, IPA.
9.45 – 10.05 a.m. - Inaugural Address by Chief Guest- Dr. Surinder Singh, Drugs Controller General of India, Govt. of India, New Delhi.
10.05 – 10.35 a.m. - Key Note Address – Dr. K. Anji Reddy, Chairman, Dr. Reddy's Laboratories, Hyderabad.
10.35 – 11.00 a.m. - Tea Break
11.00 – 11.40 a.m. - Challenges to Indian Pharmaceutical Companies catering to Global Market – Mr. G.V. Prasad, CEO, Reddy's Laboratories, Hyderabad.
11.40 - 12.20 p.m. - Quality by Design – New perspectives to product development - Dr. Vinod Arora, V. P., Pharma Research, Ranbaxy Laboratories, New Delhi.
12.20 – 1.00 p.m. - Approach to speedy entry to Global Market – Dr. Parthasarathi Reddy, C.M.D., Hetero Drugs, Hyderabad.
1.00 – 2.00 p.m. - Net working Lunch
2.00 – 2.40 p.m. - New Concept in Facility Design – Mr. Sanjit Singh Lamba, Eisai Pharma, Vishakhapatnam.
2.40 – 3.20 p.m. - IPR Issues concerning Global Pharma Market – Dr. R. Shrivastava, Head, IPR, Sun Pharma
3.20 – 3.45 p.m. - Tea Break
3.45 – 4.15 p.m. - Role of Pharmexcil in Global Pharma Marketing – Dr. P.V. Appaji, Executive Director, Pharmexcil.
4.15 – 4.30 p.m. - Concluding remarks

Organized by:
Indian Pharmaceutical Association
Supported by:
- IPA - A. P. State Branch
- Bulk Drug Manufacturers Association
- Organization of Pharmaceutical Manufacturers
- Andhra Chamber of Commerce

Registration & other details:
www.ipapharma.org