Drug Information Bulletin

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Content

Editorial

Pharmacists of India celebrated 25th September as the Pharmacists Day first time in India. Pharmacy Council of India has decided that they will celebrate this day as Pharmacists Day in India every year and requested all State Pharmacy Councils, Pharmacy Institutions and professional organizations to celebrate the occasion.

Pharmacists are one of the three main pillars of the health care systems with Doctors and Nurses. Though Doctors Day and Nurses Day are being celebrated since long back, no Pharmacists day was celebrated. This celebration will be a boost to the pharmacist as a health care provider and certainly recognition to their relentless service to the mankind.

The main objective of the celebration is to update the knowledge base of the pharmacists, awareness of common people regarding proper use of medicines, preventive measures against diseases and overall development of health care system.
IPA, Bengal Branch, has celebrated the day by distributing a badge to the Pharmacists with a request to all fellow Pharmacists to wear this badge during the working hours on 25th September. One Panel Discussion on “Concept of Ward Pharmacy and its implementation” was also organized on this occasion on 25th September 2013 at IPA Auditorium at 6.30 PM.
This day was celebrated with great enthusiasm throughout the country. There is information that Pharmacy Council of India, West Bengal Pharmacy Council, Goa Pharmacy Council along with IPA Goa Branch & Chemist & Druggists Association, Tamil Nadu Pharmacy Council, Kerala Pharmacy Council along with other institutions celebrated the occasion.
It may be noted that earlier Her Excellency President of India Mrs. Prativa Patil has declared that Govt. of India will declare a day as “Pharmacists Day” and will institute an award like- Dr. B.C. Roy Award and Florence Nightingale Award. Hope PCI and Professional organizations of our Country will pursue the matter for its quick implementation.

Diclofenac: New safety advice of European Union

The Coordination Group for Mutual Recognition and Decentralized Procedures – Human (CMDh) has endorsed new safety advice for diclofenac-containing medicines in the form of capsules, tablets, suppositories or injections. The new advice aims to minimize cardiovascular risk.

This follows a recent review by the European Medicines Agency's Pharmaco-vigilance Risk Assessment Committee (PRAC), which found that the effects of systemic diclofenac are similar to those of selective COX-2 inhibitors particularly when diclofenac is used at a high dose and for long-term treatment. The PRAC therefore recommended that the same precautions already in place should be applied to diclophenac.

Clinical-trial and epidemiological data consistently point towards an increased risk of arterial thrombotic events associated with the use of diclofenac, particularly at high dose (150 mg daily) and in long-term treatment.Use of diclofenac is contraindicated in patients with established congestive heart failure, ischaemic heart disease, peripheral arterial disease or cerebrovascular disease.Patients with significant risk factors for cardiovascular events (e.g., hypertension, hyperlipidaemia, diabetes mellitus, smoking) should only be treated with diclofenac after careful consideration.

References:

1. Krum H, Swergold G, Gammaitoni A, Peloso PM, Smugar SS, Curtis SP, Brater DC, Wang H, Kaur A, Laine L, Weir MR, Cannon CP. Blood pressure and cardiovascular outcomes in patients taking non-steroidal anti-inflammatory drugs. Cardiovasc Ther.2012;30(6): 342–350.

2. Coxib and Traditional NSAID Trialists' Collaboration. Vascular and upper gastro-intestinal effects of non-steroidal anti-inflam-matory drugs: meta-analyses of individual participant data from randomised trials. Lancet, Early Online Publication,30 May 2013 doi:10.1016/S0140-6736(13)60900-9.

3. European Medicines Agency. Press Release,28 June 2013 at http://www.ema. europa.eu ema

Ketoconazole: Fatal liver injury United States of America

The Food and Drug Administration (FDA) is taking several actions related to ketoconazole

(Nizoral®) oral tablets. These include limiting use, warning of severe liver injuries and adrenal gland problems and advising that it can lead to harmful drug interactions with other medications. The FDA has approved label changes and added a new medication guide to address these safety issues. As a result, ketoconazole oral tablets should not be considered as first-line treatment for any fungal infection. Ketoconazole should be used for the treatment of certain fungal infections, known as endemic mycoses, only when alternative antifungal therapies are not available or tolerated. Topical formulations of ketoconazole have not been associated with liver damage, adrenal problems, or drug interactions.

Ketoconazole tablets can cause liver injury, which may potentially result in liver transplantation or death. Serious liver damage has occurred in patients receiving high doses of ketoconazole for short periods of time as well as those receiving low doses for long periods. Some of these patients had no obvious risk factors for liver disease.

Ketoconazole tablets may cause adrenal insufficiency and healthcare professionals should monitor adrenal function in patients who have existing adrenal problems or in patients who are under prolonged periods of stress such as those who have had a recent major

surgery or who are under intensive care in the hospital. Ketoconazole tablets may interact with other drugs and result in serious and potentially life-threatening outcomes.

Reference:
FDA Drug Safety Communication , 26 July 2013 at
http://www.fda.gov/Drugs/DrugSafety/ucm362415.htm

Indian Government has sent out a strong message to ensure supply of Essential drugs

The Indian government has sent out a strong message to drug companies and trade channels to ensure that supply of essential drugs is unperturbed, after reports of shortage of drugs came to light id-10031083 The National Pharmaceutical Pricing Authority (NPPA) has warned that the Essential Commodities Act may be invoked against those who disrupt the supply and distribution of essential medicines Related Articles Vietnam evicts substandard imported drugs ASSOCHAM pushes for market-based drug pricing in India Pharma head arrested for illegal drug distribution Janssen seeks approval for drug resistant TB drug in EU Singapore: The new pharma policy implemented in India last month led to many media reports of shortage of essential medicines at retail outlets. Reacting to this for the first time, the Indian government has sent out a strong message to drug companies and trade channels to ensure that availability of these drugs is unperturbed. Reports had identified that supplies of popular pain relievers paracetamol and diclofenac, treatment for worms albendazole and those used in chronic ailments like cholesterol-lowering drug atorvastatin, diabetes drug metformin and blood pressure drug enalapril have been hindered post the implementation of the new policy. In a strongly worded letter to pharma companies and distribution channels, India's drug pricing regulator, the National Pharmaceutical Pricing Authority (NPPA) warned that the Essential Commodities Act may be invoked against those who disrupt the supply and distribution of essential medicines. Further, the letter stated that as per the Drug Price Control Order (DPCO) of 2013, consumers cannot be charged anything more that the price notified by the government for any drug formulation. In July, the government had prepared a National List of Essential Medicines and had notified those with ceiling prices of certain medicines from the list. NPPA's letter added that the DPCO 2013 explains how no manufacturer can refuse to sell a drug to a distributor while no distributor can withhold the sale of a drug to a consumer planning to purchase the medicine. - See more at:
http://www.biospectrumasia.com/biospectrum/news/196408/drug-companies-told-supply-essential-drugs#.UkgmvKx8FHg

More than 1,500 Americans died of Acetaminophen overdose in past decade

The Minneapolis Star Tribune "The Whistleblower" blog reported that during the last decade, "more than 1,500 Americans died…after accidentally taking too much" of the over-the-counter painkiller acetaminophen, "according to a new investigation by ProPublica."
ProPublica reported that "about 150 people die each year after accidentally ingesting too much acetaminophen, according to data from the Centers for Disease Control and Prevention." In addition, "tens of thousands more are sent to hospitals and emergency rooms for treatment from acetaminophen poisoning, studies show." As a result, the Food and Drug Administration "now calls acetaminophen toxicity a 'persistent, important public health problem.'"

FDA strengthens HBV warning of two cancer drugs

Reuters reports the Food and Drug Administration has announced that GlaxoSmithKline Plc's chronic lymphocytic leukemia (CLL) drug ofatumumab (Arzerra), and Roche Holding AG and Biogen Idec Inc's rituximab (Rituxan), will now contain black box warnings on "the risk that they may reactivate the hepatitis B virus in patients previously infected with the disease." The drugs already contain a description of the risk in the warnings section of the drugs' labels, but reactivation cases have continued to occur, prompting the increased risk warning.

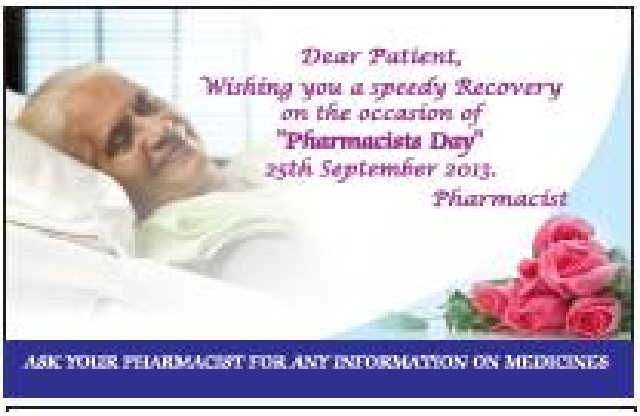
MedPage Today reports that both drugs "are anti-CD20-directed monoclonal antibodies used to treat chronic lymphocytic leukemia." Rituximab is also used for the treatment of non-Hodgkin's lymphoma, rheumatoid arthritis, and vasculitis. HBV reactivation can occur in patients previously infected "even if it resolved clinically." Over "100 possible cases of fatal HBV-associated hepatic injury associated with these agents have been identified in the FDA's Adverse Event Reporting System database."

U.S. bolsters drug-factory inspections in India

The U.S. FDA is stepping up inspections of drug-industry facilities in India and their compliance with manufacturing standards. The agency is training and enrolling more drugs investigators in the second-biggest supplier of finished dose treatments to the U.S. "Having these additional inspectors in-country will assist the agency in meeting our legislative mandates," U.S. FDA spokesman Christopher C. Kelly said. Business Standard (India)/Press Trust of India

Pics of Celebration of Pharmacists Day by IPA, Bengal Branch

Badge used by the Pharmacists at their work place



Greetings cards distributed amongst the Patients at Hospitals and Community Pharmacy

Speaker with participants at the end of the panel discussion on "Ward Pharmacy concept and its implementation" at IPA, Bengal Branch Auditorium