BRAC UNIVERSITY
Inspiring Excellence

PHARMA HIGHLIGHTS

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Participation in the Conference of Global Model United Nation

Model United Nation is a miniature of united nation activities where students from different countries play role of different delegates and stand for national as well as international issues focusing on the main agenda that is development of human life. Md. Sadman Ridwan Abid, Samanta Sifat Lamia and Nuruddin Masud; students from Pharmacy Department, BRAC University have effectively participated in the conference of Global Model United Nation that has been held in Bihar, India from 3rd to 5th July, 2015 to represent Bangladesh and Maldives on education system and human rights. The experience of attending the conference has not only enriched the knowledge beyond of academic leash but also enhanced the leadership qualities among the students.

–Samanta Sifat Lamia

Codeine Cough-and-Cold Medicines in Children: Drug Safety Communication- FDA Evaluating Potential Risk of Serious Side Effects

FDA is investigating the safety of using codeine-containing medicines to treat coughs and colds in children less than 18 years because of the potential for serious side effects, including slowed or difficult breathing. Children, especially those who already have breathing problems may be more susceptible to these serious side effects. In 2013, FDA warned against using codeine in children who recently had surgery to remove their tonsils and/or adenoids. In April 2015, the European Medicines Agency (EMA) announced that codeine must not be used to treat cough and cold in children under 12 years and that codeine is not recommended in children and adolescents between 12 and 18 years who have breathing problems, including those with asthma and other chronic breathing problems. FDA will continue to evaluate this safety issue and will consider the EMA recommendations. Final conclusions and recommendations will be communicated when the FDA review is complete. Till then parents and caregivers who notice any signs of slow or shallow breathing, difficult or noisy breathing, confusion, or unusual sleepiness in their child should stop giving their child codeine and seek medical attention immediately.

-Fabiha Tasnim

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm453379.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

Novel Ways of Treatment for Malignant Hematology

From 29th May to 2nd June 2015, the most updated research outcomes of American Society of Clinical Oncology (ASCO) were revealed in their yearly conference hosted at Chicago. The Associate Editor of NEJM Watch Journal of Oncology and Hematology, Micheal William , MD, ScN, has been keenly monitoring and updating the recent discoveries in therapeutics and medication of hematology malignancies. These details include treatment for frequently occurring myeloma and its maintenance therapy as well as treatment for lymphoma and leukemia. A humanized monoclonal antibody, etozumab is meant to bind with the surface protein SLAMFT (CS1) on all myeloma cell, excluding cytogenic sub-type. A phase III trial (with control group) etozumab in combination with lenalidomide and dexamethazone and Etozumab is proven to be a moderately safe anti-myelomal agent alone or in cluster with other medicines for cancer cases under mild therapy. Another phase II trial was conducted with daratuzamab along with proteasome inhibitors and immunomodulatory agent. This has also turned out as a success for medicating moderately-treated cases as a combination therapy with tolerable adverse effects. Observational experiments on phase III trials were carried out to work out the effectiveness of lenalidomide-based maintenance therapy. It has been found efficacious with melaphalan chemotherapy and autologous stem-cell transplantation therapy. Obinutuzamab is the type II anti-CD20 monoclonal antibody that adopts a salient process to halt the progression of rituximab-refractory indolent B cell lymphoma. Obinutuzamab was under control-based random clinical trial III as along with bendamustine when it has displayed cases of progression free survival (PFS) without much toxicity, except neutropenia. Ibrutinab is also a light of hope of patients of chronic lympholytic leukemia and small lympholytic lymphoma. It is due to its increased PFS when observed under trial III in combination with bendamustine and rituximab to compare its adverse and toxic reactions with that of placebo.

-Kasfia Tasnim Humaira

http://www.jwatch.org/na38540/2015/07/14/asco-2015-report-malignant-hematology?query=etoc_jwonchem

Odomzo®

An experimental drug sonidegib which appears to shrink tumor markedly in patients with advanced basal cell carcinoma (laBCC) according to a result published by American Society of Clinical Oncology, has recently got approved by FDA in July, 2015. Sonidegib, marketed as Odomzo® (formerly LDE225) is an oral, selective smoothened (SMO) inhibitor. SMO is a molecule that regulates the hedgehog (Hh) signaling pathway, which plays a critical role in stem cell maintenance and tissue repair, as well as in advanced basal cell carcinoma. On July 24th, 2015-Novartis has announced the confirmation of the FDA approval of Odomzo® 200 mg capsules for the treatment of adult patients with locally advanced basal cell carcinoma (laBCC) that has recurred following surgery or radiation therapy, or those who are not candidates for surgery or radiation therapy. The approval was based on the

demonstration of a durable objective response rate (ORR) in an international, multi-center, double-blind, randomized, two-arm, non-comparative trial in patients with laBCC not amenable to local therapy or metastatic basal cell carcinoma (mBCC). Objective response included complete response (clinically significant tumor response with complete absence of disease) and partial response (clinically significant tumor shrinkage). Novartis intends to release the completed results of the trial at a future date. **-Noshin Mubtasim**

http://www.fda.gov/Drugs/InformationOnDrugs/ApprovedDrugs/ucm455865.htm, http://www.drugdevelopment-technology.com/news/newsnovartis-phase-ii-trial-of-bcc-drug-sonidegib-meets-primary-endpoint-4181074

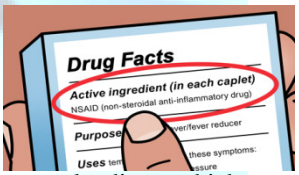
Weight Loss Products Analysed to have Concealed Drug Ingredients

Weight loss products, which are type of dietary supplements, are being widely used as OTC, especially in the western world where obesity is found to have been increasing in a considerable rate. However, consumers while using these products may not know their potential to harm their health instead of assisting them in taking care of their health. This information recently came into limelight when FDA carried out analysis of two popular weight loss products in the form of capsules named as "Akttive" and "Zero Xtreme". When analyzed they have been found to contain hidden drug elements which are either controlled substances or are not approved to be used in pharmaceuticals. Examples of such hidden ingredients are sibutramine and desmethyl-sibutramine found in both and additionally phenolphthalein in "Akttive" capsules. Sibutramine, known as an oral anorexient, acts as serotonin-norepinephrine reuptake inhibitor causing anorexia so highly preferred to be used in weight loss products. This drug was banned in 2010 after clinical studies showed that it is associated with occurrence of several cardiovascular disorders like heart attack, arrhythmia and stroke. Desmethyl-sibutramine is a metabolite of sibutramine and structurally similar to it, is likely to have same devastating effects as sibutramine. On the other hand, phenolphthalein, which falls in category of laxative has never been used in any approved drug product in USA and also has capability to lead to cancer. FDA urges consumers to be very careful not to use such tainted weight loss products, which in the name of benefit may lead to life-threatening conditions. **–Nausheen Sayeara**

http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/MedicationHealthFraud/ucm453652.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

FDA Strengthens Warning of Heart Attack and Stroke Risk from NSAIDS

Seeking relief from a headache, backache or arthritis we tend to skip on reading the important safety information on the container. The FDA is strengthening an existing warning in prescription drug labels and over-the-counter (OTC) Drug Facts labels to indicate that nonsteroidal anti-inflammatory drugs (NSAIDs) can increase the chance of heart attack or stroke. These serious side effects can occur as early as the first few weeks of using an NSAID, and the risk might rise with the duration of taking NSAIDs. The OTC drugs in this group are used for the temporary relief of minor aches and pains such as headaches, toothaches, backaches, muscular aches, tendonitis, strains, sprains and menstrual cramps, also treating several kinds of arthritis and other painful conditions. Because many prescription and OTC medicines contain NSAIDs, consumers should avoid taking multiple remedies with the same active ingredient. Common ones include ibuprofen and naproxen. FDA will request that the manufacturers of OTC NSAIDs update the heart attack and stroke risk information in Drug Facts labels. A boxed warning was added to prescription drug labels for this risk in 2005 but more recent data and information are prompting FDA to update labeling by adding information for people who already have had a heart attack or have an increased risk of having another heart attack or dying of heart attack-related causes if they're treated with NSAIDs. But the risk is also present in people without cardiovascular disease. "There is no period of use shown to be without risk," says Judy Racoosin, M.D., M.P.H., deputy director of FDA's Division of Anesthesia, Analgesia, and Addiction Products. Consumers should carefully consider whether the drug is right for them, and use the medicine only as directed. They should take the lowest effective dose for the shortest period of time possible, say experts.



All NSAIDs work by blocking hormone-like substances called prostaglandins, which are involved in pain and inflammation as well as many other bodily functions, so NSAIDs may additionally impair renal function in patients with a decreased effective circulating volume affecting the unstable cardiovascular homeostasis in these patients. Should these risks stop you from taking an NSAID for arthritis pain? That depends on how often you take them. If it's intermittently, they're probably very safe. Always consult a health care provider so they can set up the right treatment options for you.

-Labiba Mahmud

http://www.fda.gov/forconsumers/consumerupdates/ucm453610.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

FDA Takes Action against Unapproved Prescription Ear Drop Products

The U.S. Food and Drug Administration announced its intention to take enforcement action against companies that manufacture and/or distribute certain unapproved prescription ear drop products (known as otic products) labeled to relieve ear pain, infection and inflammation on July 1, 2015. The unapproved prescription ear drops contain active ingredients such as benzocaine and hydrocortisone, and have not been evaluated by the FDA for safety, effectiveness and quality. The labels on these products do not disclose that they lack FDA approval, and health care professionals may not be aware of their unapproved status. In a federal register notice published, the agency informed the companies that they must stop manufacturing these unapproved prescription otic products or be subject to enforcement actions, including seizure, injunction and/or criminal proceedings.

-Tanisha Momtaz

http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm453348.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

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