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PHARMA HIGHLIGHTS

Participation of Pharmacy Students in the 61st IPSF World Congress

The Department of Pharmacy is delighted to inform that two members from BRAC University Pharma Society (BUPS), Mr Samin Huq, IPSF Contact Person and Ms. Raihanatul Anwar, General Secretary of BUPS is going to participate in the 6st International Pharmaceutical Students' Federation (IPSF) world congress, Hyderabad, India as official delegates of BUPS and Bangladesh. It is a matter of great honour that they have been funded by Beximco Pharmaceuticals Limited, one of the leading pharmaceutical company of the country to attend this glorious event. The IPSF world congress is a 10 daylong event, where around 700 students and recent graduates across the globe gather under one roof to discuss the current burning issues of global healthcare and to participate in different events and projects of IPSF, the leading international organisation for advocacy of students and recent graduates of pharmacy and pharmaceutical sciences in the field of public health, pharmacy education and pharmacy profession development.

Bangladesh Companies Entering US Drug Market

Production of quality medicine is one of the biggest challenges in the field of global healthcare in order to meet higher demand and supply in the large market regularly. In addition to that, the companies need to maintain the quality that meets the regulatory standard of the respective country. The regulatory bodies of the world are WHO, US-FDA of USA, MHRA of UK, TGA of Australia and PMDA of Japan. US-FDA maintains the highest degree of pharmaceutical standard for the manufacture and sale of drugs and medicine in the highly controlled USA drug market. Securing an approval from regulatory agencies like US-FDA by a foreign company is not only a matter of great achievement but also a certification of providing medicine of the highest standard to the mass people. It is a matter of great pride when such approval is obtained by companies of the developing countries who are striving hard to maintain such quality standard. This is to inform everyone that two of the leading pharmaceutical companies of Bangladesh, Square Pharmaceuticals Limited and Beximco Pharmaceuticals Limited have reached such heights by passing the audit of US-FDA without the issuance of Form 483 form upon the inspection of their solid dosage facility thus facilitating the entry of Bangladesh in the US drug market. According to the Managing Director of one of the companies, Beximco Pharmaceuticals limited, Mr. Nazmul Hassan, “It is a matter of great achievement for the pharmaceutical industry of Bangladesh” He also emphasised on the approval as it will create opportunity for drug export in US as well as proof of maintaining such strict standard and quality parameters. **-Samin Huq [Source:http://www.dhakatribune.com]**

Boycott of half a dozen of detrimental drugs endorsed

All medicines do not promise to cure. Recently, six widely used generic drugs manufactured in Bangladesh, have been listed to impose dreadful effects on human beings and have been banned in our country. The article requesting the ban had been submitted to the National Adverse Drug Reaction Committee and the concluding verdict would be announced by the Central Committee, said the Director of the Directorate General of Drug Administration (DGDA), Selim Barami. A meeting was held on 12th March, 2014. On this issue senior doctors and health sector officials acknowledged the pernicious effects of the generic drugs. The drugs were already banned due to causing harmful reactions and irregular heart rhythms in countries like India, the UK, the USA, Ireland, Canada, Japan and Australia. Amongst the six drugs, two of them - Pioglitazone and Rosiglitazone - are used for type II diabetes patients. The remaining four - Flupenthixol-Melitracen, Gatifloxacin (except ophthalmic preparations), Tegaserod and Sibutramine are used for treating patient with mental diseases, bacterial infections, fractious bowel syndrome and obesity correspondingly. Even doctors have stopped prescribing Tegaserod and Sibutramine but some still go on prescribing Pioglitazone, Rosiglitazone and Gatifloxacin - said, Professor of Medicine at the DMCH, Md Faizul Alam Chowdhury. In the end, the president of Bangladesh Pharmaceuticals Society, Naser Shahriar Zahedi confirmed the ban of the drugs looking at the pros and cons ratio. **-Waseka Shams Chowdhury [Source:http://www.dhakatribune.com/]**

Savaysa: New Medication for Stroke Therapy

At the present time, one of the most common causes of death is stroke which is considered as the fifth leading cause of death for all Americans, especially in minority communities. Different types of anti-coagulant medication are used to prevent or reduce the risk of stroke. Choosing the right medication is very important for preventing stroke as some anticoagulants like aspirin have a previous history of making the situation worse. Besides that some drugs like warfarin causes major bleeding problems. Recently, in January 2015 a blood thinning medication has been approved by FDA, named Savaysa. This drug has been proved to reduce the risk of stroke in patients with atrial fibrillation (AF) and

has similar therapeutic effects to several other recently approved anti-coagulants and an older drug like warfarin. These anti-coagulants and older drugs can reduce the chance of stroke in patients with AF by more than 50% whereas in the Savaysa clinical trial, more than 21,000 people having atrial fibrillation have showed a large stroke reduction and no meaningful differences by sex, race (Whites versus Asians), or age (greater than 75 years) for the drug's performance or side effects (e.g., major bleeding). Considering all these facts it can be said that advent of Savaysa for stroke therapy is a successful initiative and it can be prove to be a potential treatment option for strokes therapy. **- Tanisha Momtaz Source:http://www.fda.gov]**

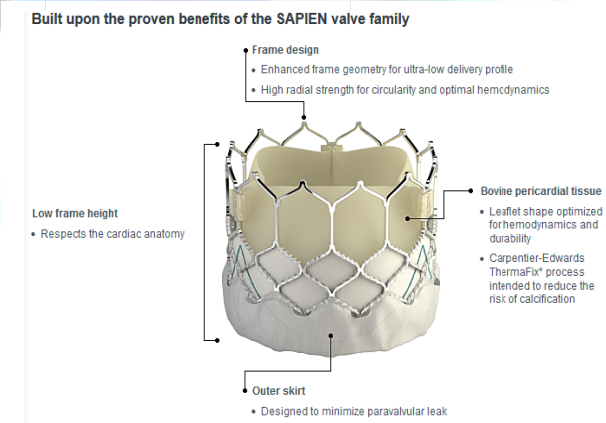
Recent Device Approvals by FDA: Dexcom G4 PLATINUM (Pediatric) Continuous Glucose Monitoring System

The FDA has recently approved the Continuous Glucose Monitoring System Dexcom G4 PLATINUM (Pediatric) to be marketed on May 22, 2015. The system is an externally-worn glucose sensor that continuously measures and displays glucose levels. In addition, the system reports trending information in real-time for up to seven days (the life of each sensor). This supplement updates the software in the pediatric version that calculates the glucose values from the sensor signal. The updated software has improved the accuracy of the system, primarily for glucose values less than or equal to 70 mg/dL. This allowed for the removal of performance warnings from the device receiver and labeling.

2-17 years old children with diabetes and their caregivers can use the tracking and trending glucose information to help them understand patterns in their glucose levels, and be alert when glucose values are approaching potentially dangerous hyperglycemic and/or hypoglycemic levels. When used along with a blood glucose meter to obtain a more accurate reading of actual blood glucose levels, the Pediatric CGM (Continuous Glucose Monitoring) System can also help children with diabetes and their caregivers make long-term adjustments to their treatment plan to keep blood glucose levels in a safe range since the Pediatric CGM System includes several components: a sensor, transmitter and receiver. The glucose sensor contains a wire that is inserted under the skin on the abdomen or upper buttock and measures glucose values in the fluid around the cells (interstitial fluid). The glucose values are sent through the transmitter to the hand-held receiver, where they are displayed for the user. On the contrary the Pediatric CGM System, sensor, transmitter, and receiver should be removed before Magnetic Resonance Imaging (MRI), Computed Tomography (CT) scan, or diathermy treatment since the System has not been tested during MRI or CT scans or with diathermy treatment. The magnetic fields and heat could damage the device so that it might not display sensor glucose readings or provide alerts, and a low or high glucose value may be missed. Furthermore children taking medicines with acetaminophen (such as Tylenol) while wearing the sensor may falsely raise a child's sensor glucose readings. The level of inaccuracy depends on the amount of acetaminophen active in a child's body and may be different for each child. **-Fabiha Tasnim. [Source:http://www.fda.gov/]**

SAPIEN 3 gets FDA approval

The U.S. Food and Drug Administration (FDA) announced approval of the Edwards SAPIEN 3 valve with the Commander Delivery System on June 17, 2015. SAPIEN 3, manufactured by Edwards Lifesciences is a global leader in the science of heart valves and hemodynamic monitoring. Aortic valve stenosis obstructs blood flow from the heart into the aorta, leading to serious problems like fainting, chest pain, heart failure, irregular heart rhythms (arrhythmias), or cardiac arrest. Patients with severe aortic valve stenosis generally need to have a heart valve replacement to improve blood flow through their aortic valve but about 30 percent of patients are considered inoperable or at high risk for surgical complications. The SAPIEN 3 valve being in the third generation of the SAPIEN THV that FDA originally approved in 2011, has a major design change making it 'better' than its former SAPIEN device. The SAPIEN 3 valve has been commercially available in Europe since January 2014. The SAPIEN family of valves has been used in the treatment of more than 100,000 patients globally. The approval was based on data from the PARTNER II S3 study, a clinical trial involving 583 patients. Martin B. Leon, MD, director of the Center for Interventional Vascular Therapy at New York-Presbyterian says, "The PARTNER II study concluded that this new valve reduced several complications associated with the Transcatheter aortic valve replacement (TAVR) procedure such as paravalvular leakage and stroke, and represented a meaningful improvement over data from prior studies with earlier-generation devices,". The rate of moderate or greater leakage through and around the valve at 30 days was significantly low i.e. 3.0% in patients treated with the SAPIEN 3 THV compared to the 14.5% in patients treated with SAPIEN THV. Patients who receive the SAPIEN 3 THV, however, also face a risk of serious complications from the implantation procedure, such as death, stroke, acute kidney injury, heart attack, bleeding, and the need for a permanent pacemaker. Patients undergoing anticoagulation/antiplatelet therapy should refrain from using SAPIEN 3 THV.



-Labiba Mahmud. [Source:http://www.fda.gov/]

Editorial Committee: Dr. Eva Rahman Kabir, Nishat Zareen Khair, Sabiha Chowdhury and Zara Sheikh.

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