Drug Information Bulletin

Drug Information Centre (DIC)
Indian Pharmaceutical Association
Bengal Branch
Tele fax: 033 24612776, E-mail: ipabengal.dic@gmail.com
Web Site: http://www.ipabengal.org
Contact: 09830136291
&
Regulatory Affairs Division (RAD), IPA

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Content

Editorial

Government of India has reduced price of coronary stents up to a tune of 85 percent is a boon to the cardiac patients. The notification No. S.O. 412(E) published on 13th February 2017 fixed price of coronary stents as follows-Bare Metal stents- Rs. 7260 and Drug Eluting Stents (DES) including metallic DES and Bioresorbable Vascular Scaffold (BSV), Biodegradable Stents at Rs. 29600, the price of which varies earlier from Rs. 35000-Rs. 45000 and Rs. 80000-Rs.175000.

This has happened due to the Hon'ble High Court of Delhi, in response to a public interest litigation filed before it seeking a direction to the Government to include 'Coronary stents' in the NLEM thereby controlling the sale of the same, issued an order dated 25.02.2015, to treat the petition as a representation and issue an appropriate order in accordance with the law. In view of the said Order, this Ministry constituted a Sub-Committee to examine the issues relating to the essentiality of coronary stents. The Sub-Committee has submitted its report to the Government and after examination of the report, the Government of India has accepted the recommendations of the Sub-Committee. The Government of India has further decided that the recommendations of the Sub-Committee with regard to inclusion of the Coronary Stents in the NLEM 2015 will be operational with immediate effect. Further the Govt. of India has included the Bare Metal stents and Drug Eluting Stents (DES) including metallic DES and Bioresorbable Vascular Scaffold (BSV), Biodegradable Stents under NLEM vide notification no. S.O.4100E on 21st December 2016 with immediate effect. Finally the notification for capping prices of coronary stents has published under DPCO. This move is welcomed by most of the stakeholders as such steps will increase access to healthcare.

Dr. Subhash C. Mandal
Editor
E mail: subhash.mandaldr@gmail.com
Mob. 9830136291

Message:

Congratulations to Drug Information Bulletin for 10 years of informing prescribers and users of medicines.
Best wishes,
Neil

Dr Neil Pakenham-Walsh MB,BS, DCH, DRCOG
Coordinator, Healthcare Information For All www.hifa.org
Co-director, Global Healthcare Information Network
Chair, Dgroups Foundation (www.dgroups.info)
Corner House, Market St
Charlbury, Oxfordshire OX7 3PN, UK

Chinese affordable lung cancer drug hits market

A generic targeted drug to treat cancer manufactured by a Chinese pharmaceutical company hit market over the weekend. The new gefitinib cancer-treating drug, whose Chinese commercial name is Yiruike, was produced by Qilu Pharmaceutical (Qilu). Its release ends an almost decade-long monopoly by Iressa, developed by British multinational biopharmaceutical company AstraZeneca and introduced to China in 2005. Yiruike was approved for marketing by China's State Food and Drug Administration after Iressa's patent protection expired in April 2016, Qilu sources said. A panel of Chinese pharmacists, headed by professor Yang Guoping with Central South University, have endorsed Yiruike.

The drug is a much-needed first line medicine used in targeted therapies against non-small-cell lung cancer, which accounts for about 80 percent of lung cancer cases in China.

Gefitinib specifically works against the epidermal growth factor receptor EGFR, whose function is to put the brakes on cell growth. In non-small-cell lung cancer, the mutation of EGFR leads to a proliferation of cells, forming fatal tumors.

Lung cancer kills more people than any other cancer in China.About 591,000 people die from lung cancer in China every year, according to the national cancer center. There are about 733,000 new cases every year. Targeted therapy has emerged over the past decade as a promising treatment for advanced lung cancer patients, those who do not respond well to chemotherapy. The price of targeted therapy drugs are exorbitant for most working class families. The gefitinib targeted therapy proved so popular that in 2014 a Chinese charity began helping lung cancer patients who could not afford to buy the drug. The cost for a week's dosage exceeds 10,000 yuan ($1,470). Qilu's general manager Li Yan said Yiruike, at less than 2,000 yuan a pack, is a fraction of the price of the previously available drug, meaning more people in need can be helped.

Ref.: Xinhua

Cipla launches Hepatitis B vaccine in India

Cipla Ltd. has launched adult Hepatitis B vaccine in India. Under a co-exclusive agreement with Serum Institute of India Private Limited (SII), Cipla will market the vaccine for adults while SII will market it for adults and children.

Umang Vohra, managing director and global chief executive officer of Cipla Ltd., said: “This agreement will enable Cipla to provide affordable vaccines for a chronic disease like Hepatitis B. Cipla’s strong marketing network and reach will ensure maximum accessibility of the vaccines in India.”

In India, around 40 million people are chronically infected with hepatitis B. This infection is responsible for 70 per cent of chronic hepatitis and 80 per cent of liver cirrhosis. Hepatitis B is spread through cont act with an infected person’s blood and body fluids. At risk are all those who are not vaccinated against the infection. Since 2002 the Hepatitis B vaccine has been a part of India’s Universal Immunization Programme.

This vaccine is able to protect 95 per cent of recipients from developing chronic Hepatitis B. The vaccine is given in three doses that include one after the first month of the first dose and the second after 6 months post the first dose. The vaccine can protect the recipient from this infection for decades. In addition, it is

expected to bring down the number of cases of liver cirrhosis and liver cancer.

Ref.: Pharmabiz

Report on ways to boost drug access approved by EU Parliament committee

A draft report recommending improvements to drug access has been approved by the European Parliament's Committee on Environment, Public Health and Food Safety. The report also called on member states to reinforce measures to achieve fair drug prices and requested the commission analyze the regulatory framework for orphan medicines.

Ref.: FDA news

Palivizumab prophylaxis may reduce later wheezing risk among preemies

A Japanese study in the American Journal of Respiratory and Critical Care Medicine found that 15.3% of preterm infants who received palivizumab prophylaxis had physician-diagnosed recurrent wheezing at six years' follow-up, compared with 31.6% of those who didn't receive treatment. However, the findings didn't show significantly different atopic asthma rates between the groups.

Ref.: MedPage Today

Fluoroquinolones Risk of retinal detachment

The HSA, has worked with marketing authorization holders to update the package inserts of fluoroquinolone-containing products (ciprofloxacin, levofloxacin, moxifloxacin, norfloxacin, pefloxacin, ofloxacin, and lomefloxacin) to warn of the potential risk of retinal detachment. The need to seek medical attention in the event of visual impairment and disturbances with these products has been highlighted.

Fluoroquinolones are broadspectrum antibiotics that are used to treat a wide range ofindications such as the infections of the urinary tract, respiratory tract, skin and soft tissue, bones and joints, and abdominal cavity. The association between oral fluoroquinolones intake and occurrence of retinal detachment has been investigated in several epidemiological studies. Two large cohort studies have found a statistically significant increased risk of retinal detachment with use of oral fluoroquinolones. The increase in risk of retinal detachment was not confirmed in other published studies as well as in a study conducted by the EMA. However, in most of these studies, the confidence intervals of the calculated risks were relatively wide, thus a small increase in risk cannot be excluded.

The HSA has not received any reports of retinal detachment associated with the use of fluoroquinolones, but has received several reports describing visual disturbances such as blurred vision, eye redness, itching and conjunctivitis. Since retinal detachment is serious and its association with oral fluoroquinolones use cannot be ruled out, the HAS has advised that health-care professionals should consider this potential risk when prescribing and dispensing fluoroquinolones to patients.

Reference: *http://www.hsa.gov.sg/*

Pioglitazone containing medicines: Risk of bladder cancer

The US FDA has updated the product information for pioglitazone-containing medicines (Actos®, Actoplus Met®, Duetact®, Oseni®), to include an additional description of studies to existing warnings, about the increased risk of bladder cancer. Pioglitazone is approved to improve blood sugar control, along with diet and exercise, in adults with type 2 diabetes.

The FDA has alerted the public about the possible risk of bladder cancer in September 2010 and June 2011 based on interim results from a 10-year epidemiologic study. The FDA changed the labels of pioglitazone-containing medicines in August 2011 to include warnings about this risk,

and required the manufacturer to modify and continue the 10- year study. As a result of an updated review, the FDA has concluded that use of the type 2 diabetes medicine pioglitazone may be linked to an increased risk of bladder cancer. The FDA has recommended that health-care professionals should not use pioglitazone in patients with active bladder cancer, and should carefully consider the benefits and risks before using pioglitazone in patients with a history of bladder cancer.

Reference: *www.fda.gov*

Carbamazepine HLA-B*1502 genotyping to minimize carbamazepine induced severe cutaneous adverse reactions

The HSA has reminded health-care professionals of the recommendation for HLAB* 1502 genotyping prior to the initiation of carbamazepine (CBZ; Tegretol® and generics) therapy in patients of Asian ancestry, to minimize risk of severe cutaneous adverse reactions (SCARs). This recommendation was stated in a joint Dear Health-care Professional Letter by the Ministry of Health and the HAS in April 2013. CBZ is an anticonvulsant indicated for the treatment of epilepsy and other conditions such as bipolar disorders, alcohol-withdrawal syndrome, trigeminal neuralgia, diabetic neuropathy and diabetes insipidus. Between 2003 to 2012, the HSA received an average of 15 reports of CBZ-induced Stevens Johnson Syndrome/Toxic Epidermal Necrolysis (SJS/TEN) per year.

Since April 2013, more than 2,700 patients have been genotyped for HLA-B*1502, of which 11% were found to carry the HLA-B*1502 allele. The HSA has recently received one report of CBZ-induced SJS among all the patients screened for the allele. The suspected case of CBZ-induced SJS occurred in a patient who was genotyped negative. While genotyping for HLAB* 1502 has successfully mitigated the risk of CBZinduced SJS/TEN in Singapore, it has not been shown to be a risk predictor for CBZ-induced Drug Reaction with Eosinophilia and Systematic Syndrome (DRESS). The HSA has received two cases of DRESS in patients who were genotyped negative. These cases of CBZinduced SCAR are a reminder of the need to remain vigilant for SCAR even among those who tested negative for HLAB* 1502, as non-genetic factors may be involved in the development of SCAR. HLA-B*1502 genotyping test has proven highly effective in distinguishing high-risk patients from low-risk patients who can continue to use this cost-effective medicine.

Reference: http://www.hsa.gov.sg/

Levetiracetam Risk of acute kidney injury

Health Canada has worked with manufacturers to update the safety information for all levetiracetam-containing products to reflect the potential risk of acute kidney injury, using the same wording as the product brand (Keppra®). Levetiracetam is a prescription drug used as adjuvant anticonvulsant. Health Canada reviewed the potential risk of acute kidney injury with the use of levetiracetam, following the publication of an article by the World Health Organization (WHO) that suggested this risk. At the time of the review, Health Canada had not received any Canadian reports of acute kidney injury related to levetiracetam use. A search in the WHO Global ICSR database, VigiBase®, found more than 150 international reports of acute kidney injury with the use of levetiracetam. The WHO reviewed 39 of these 150 reports in depth and concluded that levetiracetam had possibly caused acute kidney injury. In addition, there were six cases of acute kidney injury linked to the use of levetiracetam, published in the scientific literature. While the cases noted other factors such as pre-existing diseases, other medications taken at the same time, or other additional medical conditions, a link between the use of levetiracetam and acute kidney injury could not be ruled out. Health Canada's review has concluded that there may be a link between the use of levetiracetam and the risk of acute kidney injury. The current product information for Keppra® informs that cases of acute kidney injury have been reported in patients treated with levetiracetam. Health Canada has requested that the other manufacturers of levetiracetam-containing products also update their product information with the same wording.

Reference: www.hc-sc.gc.ca