Drug Information Bulletin

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Editorial

It is my proud privilege to write the editorial of the first issue of the 10th year of the Drug Information Bulletin (DIB). This bulletin started its journey nine years back on April 2007 under the Drug Information Centre (DIC), IPA Bengal Branch. Initially it started as a weekly bulletin and continued for eight years; thereafter this bulletin is being published on a weekly basis. Initially it was sent to the members of IPA Bengal Branch, but on request it expanded its horizon including IPA members of the entire country and now is available globally to anyone interested to receiving it. During the last two years it has been a joint publication of Drug Information Centre (DIC), IPA Bengal & Regulatory Affairs Division of IPA. It has earned several accolades to its credit and the latest one from Health Information for All, UK.

On completion of each year we conduct a survey among the readers through a structured questionnaire regarding their opinion on its content regularity, its quality. We are happy we have always received encouraging results and inputs. The inputs we received have been implemented as far as possible.

The most satisfying fact is that a good number of electronic bulletins have been published during last couple of years by the individuals who were the readers of this bulletin. It has also been reported that a number of Group of Hospitals both in India and abroad are forwarding this bulletin amongst their doctors, pharmacists and nurses. Some of the pharmacy & medical colleges are keeping the printed copy of this bulletin in their library for archiving. Our reader base is growing day by day on request from health personnel and even lay persons from India and abroad.

We expect your inputs to serve you better.

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Allopurinol: Interaction with 6-mercaptopurine and Azathioprine

The TGA has issued a reminder to health professionals that concomitant use of allopurinol with 6- mercaptopurine or azathioprine should be avoided, due to increased risk of potentially fatal bone marrow toxicities and blood dyscrasias. Allopurinol is an anti-uricaemic agent used to treat gout, uric acid nephrolithiasis and hyperuricaemia, including the prevention of tumour-lysis syndrome. Azathioprine is used as an immunosuppressant and 6-mercapotpurine as a cytotoxic agent. Allopurinol reduces metabolism of 6-mercaptopurine and azathioprine, increasing the risk of bone marrow toxicities and blood dyscrasias, such as leukopenia, thrombocytopenia and pancytopenia. If co-administration of allopurinol with 6- mercaptopurine or azathioprine is necessary, the dose of 6-mercaptopurine or azathioprine should be reduced to one quarter of the normal dose and the patient's complete blood count should be closely monitored in accordance with the product information. The TGA recommends that, health professionals should check if patients are being treated with allopurinol when prescribing azathioprine or 6-mercaptopurine, and they should educate patients about this medicine interaction.

Reference: Medicines Safety Update, TGA, Vol. 6, No. 6, December 2015 (www.tga.gov.au)

Codeine: Risk of serious breathing problems in children and adolescents

Canada Health Canada maintains its recommendation that codeine prescription products should not be recommended in children less than 12 years of age following a new review assessing the risk of breathing problems in children and adolescents treated with codeine prescription products for cough. Codeine containing products (alone or in combination with acetaminophen or aspirin in some cough and cold medication) are approved for use in adults and children ≥12 years to treat pain and reduce cough. Caution is advised regarding the use of codeine in patients with breathing conditions, including children. Codeine is converted to morphine in the liver. Due to genetic variations of liver enzymes some people can convert codeine to morphine faster and more completely than others, which can result in high levels of morphine in the blood leading to breathing difficulties and death. Health Canada conducted a new safety review to further assess the risk of serious breathing problems in children and adolescents treated with codeine prescription products for cough following emergence of new evidence. At the time of the current review, no cases of these drug-adverse events in children and adolescents were reported. Since the initial review in 2013, one international case was published in the literature, which resulted in the death of a six-year old patient, however a causal link could not be concluded. 15•WHO Pharmaceuticals Newsletter No. 1, 2016 Safety of Medicines No modifications were recommended to the Canadian prescribing information.

Reference: Summary Safety Review, Health Canada, 9 December 2015 (www.hc-sc.gc.ca)

Finasteride: Risk of suicidal thoughts and behaviour

A Health Canada review of data considers that the evidence of suicidal thoughts and behaviour associated with use of finasteride (Proscar® and Propecia®) is limited. Finasteride is used to treat and control benign prostatic hyperplasia (non-

cancerous enlargement of the prostate gland). In addition, at a lower dose, it is used to treat male pattern hair loss. At the time of the review, 11 reports of suicide related adverse effects were reported to Health Canada, and 170 to the WHO global database of Individual Case Safety Reports (ICSRs). Six of the cases reported to Health Canada described factors that appeared to be related to finasteride, however the remaining reports and reports in the WHO global database data were not robust to form a conclusion. Reports in the medical literature describe a potential link between finasteride and suicidality, however studies were few, used small number of patients, had limitations and were inconclusive. Currently, the prescribing information for finasteride lists depression as an adverse effect. Health Canada will publish a Health Product InfoWatch article to inform Canadians of the safety review, and will continue to monitor safety information involving finasteride.
Reference: Summary Safety Review, Health Canada, 17 December 2015 (www.hc-sc.gc.ca)

FDA: Some Type 2 Diabetes Drugs May Increase Risk of Heart Failure

The US Food and Drug Administration (FDA) on Tuesday updated its safety communication for Type 2 diabetes medicines containing saxagliptin and alogliptin as they may increase the risk of heart failure, particularly in patients who already have heart or kidney disease.FDA has added new warnings to the following drug labels about this safety issue: AstraZeneca's Onglyza (saxagliptin) AstraZeneca's Kombiglyze XR (saxagliptin and metformin extended release) Takeda's Nesina (alogliptin) Takeda's Kazano (alogliptin and metformin) Takeda's Oseni (alogliptin and pioglitazone)Takeda and AstraZeneca told Focus that they are aware of the label changes.The decision to update the labels was based on the evaluation of two large clinical trials conducted in patients with heart disease that were discussed at FDA's Endocrinologic and Metabolic Drugs Advisory Committee meeting last April."Each trial showed that more patients who received saxagliptin- or alogliptin-containing medicines were hospitalized for heart failure compared to patients who received an inactive treatment called a placebo," FDA said. "In the saxagliptin trial, 3.5% of patients who received the drug were hospitalized for heart failure versus 2.8% of patients who received a placebo. This is the same as 35 out of every 1,000 patients compared to 28 out of every 1,000 patients. Risk factors included a history of heart failure or kidney impairment. In the alogliptin trial, 3.9% of alogliptin-treated patients were hospitalized for heart failure versus 3.3% in the placebo group. This is the same as 39 out of every 1,000 patients compared to 33 out of every 1,000 patients."The agency is asking health professionals and patients to report side effects involving saxagliptin and alogliptin, or any other medicines, to the FDA MedWatch program. A previous safety communication was issued on 11 February 2014.FDA Drug Safety Communication: FDA adds warnings about heart failure risk to labels of type 2 diabetes medicines containing saxagliptin and alogliptin.
For details: http://www.raps.org/Regulatory-Focus/News/2016/04/05/24706/FDA-Some-Type-2-Diabetes-Drugs-May-Increase-Risk-of-Heart-Failure/#sthash.3VuTqE5z.dpuf

GSK unveils access plan for low-income countries

Will file patents for its drugs according to each country's 'economic maturity'

GlaxoSmithKline has said it will not file patents for drugs in the world's poorest countries in order to improve access to its products.

The company said it will instead pitch its approach to intellectual property in a country to reflect its "economic maturity".

There will be free generic competition in least-developed countries (LDCs), while GSK will seek patents in lower middle-income countries (LMICs) but will license rights to generic manufacturers for a 10-year period in return for a modest royalty.

The company's chief executive Sir Andrew Witty - who will step down next year - announced the measure just ahead of the UN High Level Panel on Access to Medicines yesterday.

GSK already has a good track record on medicines access, ranking at number one in the biannual Access To Medicines Index (ATMI) - funded by the Bill & Melinda Gates Foundation and the UK and Dutch governments - four times in a row.

The company has implemented several other programmes to expand access, including tiered pricing and building healthcare infrastructure.

GSK also said it plans to commit its future portfolio of cancer treatments to patent pooling and will explore the concept with the Medicines Patent Pool (MPP) - which currently focuses on HIV, TB and hepatitis C drugs - "to help address the increasing burden of cancer in developing countries".

The MPP was set up in 2010 and focuses on voluntary licensing agreements with companies serving in low-income countries and LMICs.

Other companies that have announced initiatives to improve access to medicines in poorer countries include Novartis, which recently announced plans to make 15 of its medicines available for just $1 a month.

Another firm active in this area is Gilead Sciences, which signed licensing deals with Indian generics companies to expand access to its hepatitis C therapy Sovaldi (sofosbuvir).

The intellectual property measure is the latest in a series of initiatives at GSK seeking to change the way the company does business - and patch up its reputation in the wake of a high-profile corruption scandal in China that resulted in a $487m fine in 2014.

Other changes to its practices include removing sales targets for reps and a gradual move towards stopping direct payments to healthcare professionals (HCPs) for speaking at and attending medical conferences.

Ref.: PMLive.com (U.K.)

Photograph of World Health Day Celebration by IPA, Bengal Branch

Newly elected council of IPA 2016-2018