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

Volume: 08 ***Number: 12*** ***14th September 2014***

Content

Editorial

Recently Indian Pharmaceutical Association (IPA) requested the Union Health Minister to include Bachelor of Pharmacy (B. Pharm.) as one of the qualifying subjects by amending Rule 2.1.3 and 2.1.4 of Food Safety and Standards Rules 2011.

Rule 2.1.3 of Food Safety and Standards Rules 2011 prescribed that "Food Safety Officer shall be a whole time officer and shall, on the date on which he is so appointed, possess the following:
i. a degree in Food Technology or Dairy Technology or Biotechnology or Oil Technology or Agricultural Science or Veterinary Sciences or Bio-Chemistry or Microbiology or Masters Degree in Chemistry or degree in medicine from a recognized University, or
ii. any other equivalent/recognized qualification notified by the Central Government, and
iii. has successfully completed training as specified by the Food Authority in a recognized institute or Institution approved for the purpose."

And Rule 2.1.4 of Food Safety and Standards Rules 2011 prescribed that "A person shall not be qualified for appointment as Food Analyst under the Act unless she/he ;-
i. Holds a Master's degree in Chemistry or Biochemistry or microbiology or Dairy Chemistry or Food Technology, Food and Nutrition or holds Bachelor of Technology in Dairy/Oil or holds degree in Veterinary Sciences from a university established in India by law or is an associate of the Institution of Chemists (India) by examination in the section of Food Analysts conducted by the Institution of Chemists (India) or any other equivalent qualification recognized and notified by the Central government for such purposes and has not less than three years experience in the analysis of food; and ii. Has been declared qualified for appointment as a Food Analyst by a board appointed and notified by the Authority "
It is surprising that a host of personnel having various qualification in Science, Medicine, Agriculture, Biotechnology and even Associate of the Institution of Chemists are qualified for the above post, but unfortunately Bachelor of Pharmacy has not found a place in it. It is a fact that Pharmacy course curriculum and training is one of best suitable degrees for performing the duties of Food Safety Officers and Food Analyst. B.Pharm qualified personnel have showed their competence in these areas in the past.
Hope, Union Minister of Health will be kind enough to consider the appeal of IPA for better implementation of Food Safety Act 2006.

Dr. Subhash C. Mandal
Editor

New Drug: Macitentan

Approved indication: pulmonary arterial hypertension
Opsumit (Actelion)
10 mg film-coated tablets
Pulmonary arterial hypertension can cause dyspnoea on exertion and leads to right heart failure. It can be idiopathic and familial or can be associated with connective tissue diseases and congenital heart disease with repaired shunts.

The available treatments for pulmonary arterial hypertension include calcium channel blockers, endothelin antagonists, phosphodiesterase 5 inhibitors and prostacyclins. Some patients require combinations of these drugs and some will not respond and will need a lung transplant.

Macitentan was developed by modifying the structure of the endothelin receptor antagonist bosentan. It stops endothelin from binding to the endothelin A and B receptors. These receptors are associated with vasoconstriction. Although the maximum plasma concentration is reached eight hours after an oral dose, macitentan has a rapid onset of effect. The drug is metabolised, mainly by cytochrome P450 3A4, to form an active metabolite. Macitentan has a half-life of 16 hours and its active metabolite has a half-life of 48 hours. Most of the metabolites are excreted in the urine.

The main trial of macitentan involved 742 patients with an average age of 45.6 years. Most of the patients had idiopathic or heritable pulmonary arterial hypertension or an associated connective tissue disease. They were randomised to start macitentan 3 mg or 10 mg, or a placebo, once daily. Other treatments for pulmonary arterial hypertension could be continued. The primary end point of the study was a composite of clinically worsening pulmonary arterial hypertension, the need for prostanoids, lung transplant or death.1

After median treatment duration of 115 weeks, one of these events had occurred in 38% of the macitentan 3 mg group, 31.4% of the 10 mg group and 46.4% of the placebo group. Another composite end point of death or hospitalisation for pulmonary arterial hypertension was reached by 26% of the 3 mg group, 20.7% of the 10 mg group and 33.6% of the placebo group. The advantages of macitentan over placebo in these composite end points were statistically significant.There were also improvements in exercise capacity.1

Adverse events led to treatment discontinuation in 13.6% of the 3 mg group, 10.7% of the 10 mg group and 12.4% of the placebo group. Compared with placebo, patients taking macitentan 10 mg (the dose recommended in Australia) more frequently developed respiratory infections, headache and anaemia.1 The blood count should be measured before and during treatment. As liver function can be affected, macitentan is contraindicated in patients with aminotransferase concentrations greater than three times the upper limit of normal. Monthly monitoring of liver function is recommended. Patients with renal impairment may have an increased risk of hypotension or anaemia. Macitentan is teratogenic.

Although exercise tolerance improved with macitentan, the increase was relatively small. At the start of the study the patients could walk an average of 360 metres in six minutes. After six months the patients taking macitentan 10 mg could walk 12.5 metres further.1 As this change may not be a good surrogate for

clinical outcomes, it is important that mortality was studied. However, the drug did not have a significant effect on all components of the primary composite outcome. Most of the benefit was due to macitentan 10 mg reducing the proportion of patients with worsening pulmonary arterial hypertension. Deaths from any cause and from pulmonary arterial hypertension were not significantly different from placebo.1

REFERENCE:

1. Pulido T, Adzerikho I, Channick RN, Delcroix M, Galiè N, Ghofrani HA, et al. Macitentan and morbidity and mortality in pulmonary arterial hypertension. N Engl J Med 2013; 369:809-18.

Ref. *Aust Prescr 2014; 37:139-43*

2nd National Pharmacists Day Celebration

25th September 2014

Organized by:

IPA Bengal Branch

- Public Awareness programme "KYM"
- Wishing recovery to Hospital Patients
- Seminar on " Prevention and Care of Japanese Encephalitis and related Diseases"
  Venue: IPA Auditorium
  Date: 25.09.2014
  Time: 6.30 pm

Multivitamin Capsules require to be manufacture and sell as per the provisions of the Drugs and Cosmetics Acts – The High Court of Jharkhand at Ranchi

In a recent judgment in a case filled by Mr. Sujit Kumar the then Inspector of Jharkhand, opined that the multivitamin Capsules require to be manufacture and sold under the provisions of the Drugs and Cosmetics Act. The inspector has complained against marketing of Multivitamin capsules as Food Supplement. This judgement stops converting some drugs into food supplement overnight leading to less or no control over such products, which is a potential threat to the health of the people. Copy of the judgement is available with the editor.

Drug price monitoring cells across states soon

The National Pharmaceutical Pricing Authority (NPPA) is planning to set up its units across the country. These cells will be formed in coordination with state governments and work in association with the local drug controller.

The idea is to keep a close watch on real-time price movements, the maximum retail price of medicines and their availability.

Currently, a lack of field inspectors does not allow the regulator to keep a tab on pharma companies or retailers flouting price caps. Recovery of overcharged amounts also becomes difficult for the regulator without a physical presence in a state.

NPPA says companies have overcharged consumers a total of Rs 417 crore on sale of medicines in 2014 so far. It has recovered only Rs 67 crore of this. Similarly, the overcharging during 2013-14 is put at Rs 385 crore. The proposed price monitoring cells are likely to be set up within each state's drug regulator's office. The official says a start will be made in metropolitan cities and in states where the presence of pharma units is more. Expenditure on infrastructure and personnel will be borne by NPPA; states might have to provide the space for setting up an office within the local drugregulator's premises.

To deliberate on this, NPPA recently had

a meeting with a few state drug controllers, including.

Of late, NPPA has taken some tough stands to ensure the prices of essentials, plus medicines for widely prevalent diseases, are priced reasonably. It had also taken steps to ensure no discrepancy in prices because of branding.

Ref. Business Standard

Statins don't up Diabetic Microvascular Disease Risk

Statins do not raise the risk of microvascular disease in people who took the drugs prior to being diagnosed with diabetes, a large new database analysis from Denmark suggests.

The findings were published online September 9, 2014 in *Lancet Diabetes & Endocrinology* by Sune F. Neilsen, PhD, and Børge G. Nordestgaard, MD, faculty of health and medical sciences, University of Copenhagen, Denmark.

Concern has been raised in recent years that statins might increase the risk for development of type 2 diabetes.

But this new study of nearly 63,000 individuals actually showed a statistically significantly lower cumulative incidence of diabetic retinopathy, neuropathy, and foot gangrene among diabetes patients who began using statins prior to their diabetes diagnosis, compared with those who did not use statins before developing diabetes.

While the results may be reassuring that statins don't raise the risk for microvascular disease, they aren't sufficient to support a claim of protection, Dr. Nordestgaard told *Medscape Medical News*.

"Our data are observational using national Danish registries and are not from a randomized double-blind study. Data like ours are prone to various biases and to confounding, which we have done our utmost to make sure cannot explain our results. Nevertheless, we think it is best not to be too strong-minded about what can be concluded."

Indeed, editorialist David Preiss, clinical senior lecturer in clinical biochemistry and metabolic medicine at the British Heart Foundation, Glasgow Cardiovascular Research Centre, University of Glasgow, Scotland, writes, "Pharmacoepidemiological studies need cautious interpretation and can only be regarded as hypothesis-generating....For now, any benefit of statins on microvascular complications remains unproven."

Platinum Jubilee Celebration of IPA cum NPW celebration
15th – 23rd November 2014

Organized by: IPA Bengal Branch

Platinum Jubilee Celebration

Inauguration: 15th November 2014

National Workshop: 16th November 2014

National Pharmacy Week Celebration

- Inauguration: Concurrently with Platinum Jubilee Celebration
- Different programmes throughout the week

"Utmost" Effort to Eliminate Bias

The study population, from the Danish Patient Registry, comprised 15,679 randomly-selected statin users and 47,037 statin nonusers aged 40 and older in whom diabetes was diagnosed between 1996 and 2009.

The statin nonusers were matched with the users for sex, age at subsequent diabetes diagnosis, year of diabetes diagnosis, and history of cardiovascular disease. All users had been taking statins prior to the diabetes diagnosis, in order to rule out the bias that the diabetes diagnosis would prompt a statin prescription. In a median follow-up of 2.7 years, diabetic retinopathy developed in 2866 patients, diabetic neuropathy in 1406, diabetic nephropathy in 1248, and gangrene of the foot in 2392.