Drug Information Bulletin

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Editorial

World Health Organizations (WHO) declared 14th November as World Diabetes Day to generate awareness against this killer disease. Incidence of diabetes is very high worldwide especially in developing countries. 347 million people worldwide have diabetes in 2004. In 2004, an estimated 3.4 million people died from consequences of high fasting blood sugar. More than 80% of diabetes deaths occur in low- and middle-income countries. WHO projects that diabetes will be the 7th leading cause of death in 2030. Diabetes has emerged as a major healthcare problem in India. According to Diabetes Atlas published by the International Diabetes Federation (IDF), there were an estimated 40 million persons with diabetes in India in 2007 and this number is predicted to rise to almost 70 million people by 2025. The countries with the largest number of diabetic people will be India, China and USA by 2030. It is estimated that every fifth person with diabetes will be an Indian.

Over time, diabetes can damage the heart, blood vessels, eyes, kidneys, and nerves. Diabetes increases the risk of heart disease and stroke. 50% of people with diabetes die of cardiovascular disease (primarily heart disease and stroke). Combined with reduced blood flow, neuropathy (nerve damage) in the feet increases the chance of foot ulcers, infection and eventual need for limb amputation. Diabetic retinopathy is an important cause of blindness, and occurs as a result of long-term accumulated damage to the small blood vessels in the retina. One percent of global blindness can be attributed to diabetes. Diabetes is among the leading causes of kidney failure. The overall risk of dying among people with diabetes is at least double the risk of their peers without diabetes.

Simple lifestyle measures have been shown to be effective in preventing or delaying the onset of type 2 diabetes. To help prevent type 2 diabetes and its complications, people should achieve and maintain healthy body weight; be physically active – at least 30 minutes of regular, moderate-intensity activity on most days. More activity is required for weight control; eat a healthy diet of between three and five servings of fruit and vegetables a day and reduce sugar and saturated fats intake; avoid tobacco use – smoking increases the risk of cardiovascular diseases.

Celebrate Diabetes Day on 14th to increase awareness about diabetes and care to manage it. Healthy diet, regular physical activity, maintaining a normal body weight and avoiding tobacco use can prevent or delay the onset of type 2 diabetes.

7th Edition of IP 2014 Released effective from 1st January 2014

The Union Health and Family Welfare Minister, Shri Ghulam Nabi Azad released the 7th edition of Indian Pharmacopoeia 2014 – a book of Drug Standards at the Nirman Bhawan, on 4th November 2013.

The Minister congratulated the Indian Pharmacopoeia Commission and the expert members of the Scientific Body, IPC staff and various other professionals and organizations for this achievement.

Speaking at the occasion, Shri Azad said that there have been rapid changes in the standards of drug all over the world and to keep pace with the regulatory requirements, it was felt necessary by all the stakeholders to bring out the new edition of the Indian Pharmacopoeia 2014 at the earliest. The standards given in this pharmacopoeia are authoritative, legally enforceable and intended to help in the inspection and licensing of manufacturing units and distribution of drugs and pharmaceuticals. He noted that Indian Pharmacopoeia 2014 has been considerably revised and improved by introducing advanced technology and experimental methods widely adopted in India and abroad.

Shri Azad hoped that the Indian Pharmacopoeia 2014 will be able to fulfill the mission of the Indian Pharmacopoeia Commission to promote public health, both in India and other countries using drugs manufactured in India.

The seventh edition of the Indian Pharmacopoeia (IP 2014) has been published by the Indian Pharmacopoeia Commission (IPC) in fulfillment of the requirements of the Drugs and Cosmetics Act, 1940 and Rules thereunder. It prescribes the standards for drugs produced and/or marketed in India and thus contributes in the control and assurance of the quality of the medicines.

The Indian Pharmacopoeia 2014 is presented in four volumes. The scope of the Pharmacopoeia has been extended to include products of biotechnology, indigenous herbs and herbal products, veterinary vaccines and additional antiretroviral drugs and formulations, inclusive of commonly used fixed-dose combinations. Standards for new drugs and drugs used under National Health Programmes are added and the drugs as well as their formulations not in use now a days are omitted from this edition.

The IP 2014 incorporates 2548 monographs of drugs out of which 577 are new monographs consisting of APIs, excipients, dosage forms, antibiotic monographs, insulin products and herbal products etc. 19 New Radiopharmaceutical Monographs and 1 General chapter is first time being included in this edition. It is hoped that this edition would play a significant role in improving the quality of medicines which in turn promote public health and accelerate the growth and development of Pharma Sector.

Present at the occasion were Shri K.N Desiraju, Secretary, Health & Family Welfare, Dr. V.M Katoch, Secretary, Department of Health Research & DG, ICMR, Dr Nata Menabde, WHO Representative and various other dignitaries.

PRAC recommends suspension of Diacerein-containing medicines

The EMA's Pharmacovigilance Risk Assessment Committee (PRAC) has recommended the suspension of diacerein-containing medicines across the

EU. This follows a review which concluded that the benefits of diacerein, used to treat symptoms of osteoarthritis and other degenerative joint diseases, did not outweigh its risks, particularly the risk of severe diarrhoea and potentially harmful effects on the liver.

The review was conducted at the request of the French medicines agency (ANSM) over concerns about the frequency and severity of gastro-intestinal side effects such as diarrhoea and liver disorders. In addition, the French agency considered the evidence of diacerein's benefit in osteoarthritis to be weak.

Although diacerein is known to cause diarrhoea as a side effect, the PRAC concluded that there was a high number of cases, particularly of severe diarrhoea, which sometimes led to complications. The Committee was also concerned about liver problems that had been reported in some patients taking the medicine.

With regard to benefits, the PRAC considered that the available data showed the benefits of diacerein to be limited and it concluded that the benefits did not outweigh its risks. The PRAC therefore recommended that diacerein-containing medicines be suspended in the EU until convincing evidence of a positive benefit-risk balance in a specific patient population is provided.

The PRAC recommendation will now be sent to the Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) for consideration at its meeting on 16-18 December 2013.*

Ref. pharmalive.com

Sun Pharma clinical work at Lab is halted

The Drug Controller General of India ordered Sun Pharmaceuticals, which is one of the country's largest drug makers, to suspend clinical research activities at a key laboratory in Mumbai, according to reports.

The regulator took this step after discovering that Sun did not have needed approval from the central government to operate the lab, The Economic Times writes. And the DCGI will not accept any future applications or process existing new filings made by the Mumbai lab until Sun receives formal approval, the paper adds. It is not clear if the move will affect new filings in other countries.

The move comes after the Indian Supreme Court earlier this year slammed regulators for shoddy oversight that was creating "havoc" and for going into a "deep slumber" that was placing participants at risk. A government committee report found that between January 2008 and October 2010, regulators approved 33 new drugs without trials on Indian patients (back story).

There has been ongoing controversy that drug makers have taken advantage by providing inadequate informed consent or that compensation for harm was sometimes not paid or negligible. There have also been reports of a rising number of deaths during studies (see this). The Indian health ministry reportedly acknowledged that 2,644 people died during clinical trials of 475 new drugs from 2005 to 2012.

These developments occur as the Indian pharmaceutical industry is increasingly scrutinized by other governments. The UK's Medicines and Healthcare Products Regulatory Agency tagged Wockhardt for manufacturing problems at a key facility (see this). The FDA recently issued an Import Alert on products made at a Ranbaxy plant; two others remain the focus of a consent decree (look here).

And the NIH is believed to have withdrawn funding for trials in India due to what is called an unstable regulatory environment.

The move by Indian regulators against Sun, coupled with the recent chain of events, has rattled Indian drugmaker**s.** "Given the recent developments, the fear is that regulations should not be a knee jerk reaction to activism," Suneela Thatte, President of Indian Society of Clinical Research, tells The Business Standard. The paper notes that more than 150 applications for clinical trials seeking approvals are pending with the DCGI, but so far this year, only five have been approved.

Meanwhile, multi-national drug makers and contract research organizations have slowed the pace of their studies in response to tighter policies. Drug makers conducted 262 trials last year, down from 321 during the previous year and 500 in 2010, according to The Wall Street Journal, citing government data. So far, the government approved the start of 56 trials. And drug makers are running 2,247 trials in India, which is about half the number of studies taking place in China or South Korea.

Forthcoming Events

One Day Workshop on

"Clinical Trial: Recent Development in Science and Regulation"

18th November 2013

at

The Peerless Inn, Senate-1, Kolkata

Organized By:

Indian Pharmaceutical Association, Bengal Branch

Collaborator:

Sanofi India Ltd.

Registration:

Rs. 2000 per participant

Rs. 1500 per participants (IPA Members)

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52nd National Pharmacy Week Celebration

Inaugural Programme

Date:

17th November 2013 (Sunday)

Venue:

Shri Shiskhayatan School Auditorium, 11 Lord Sinha Road, Kolkata-700071

Time: 10.00 am

Organizer:

IPA, Bengal Branch

Other Programmes:

18.11.2013:

CIPT- Uluberia-National Seminar on "Pharmacy Regulation-Meeting the demand of our Nation"

19.11.2013:

Seminar at Siliguri

20.11.2013:

Students Day -NSHM College of Pharmacy-

21.11.2013:

Hospital Pharmacy Day-Swasthya Bhaban-

23.11.2013:

Cultural Programme, Kolkata

24.11.2013:

DSP, Steel Club-Seminar