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

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Editorial

Indian Pharmacists are going to celebrate National Pharmacy Week starting from tomorrow in successive 52nd years to project the role played by the pharmacist in the health care system in our country. Though there are deficit in healthcare professionals in developing countries, but the situation with regards to Pharmacists in India is quite better. Presently more than 60, 000 pharmacists are coming out of educational institutions yearly, but unfortunately their potential are not being properly utilized. It was also felt that the quality of education require to be updated as per the present societal requirements. Pharmacists are rarely involved in framing the healthcare policy of the country and even in the policy making in a hospital. Drugs and Therapeutics Committee, Hospital formulary is rarely found in hospitals and pharmacists are rarely involved in this committee.

Recently pharmacists are being utilized in the National Rural Health Mission (NRHM). Revised National Tuberculosis Control Programme (RNTCP). National Pharmaceutical Associations are being taken in confidence recently. Indian Pharmaceutical Association has been invited to join in a workshop on MDG 4 & MDG 5 by PMNCH at Dhaka to formulate plan to achieve its goal by 2015.

MOU signed by the TBC, Govt. of India and the Indian Pharmaceutical Association and preparing a Training Module for Community Pharmacy jointly is a landmark event to involve pharmacists in National health care programmes.

It is felt that proper utilization of the pharmacists would help to improve the health care system of our country.

Hope this week long programme will be able to impress our society about the important role played by them and convenience the policy makers to utilize pharmacists properly in the health care society.

Health ministry to ban all hazardous and doubtful therapeutic efficacy drugs in market

The Union health ministry will soon ban all the hazardous and irrational drugs in the pharmaceutical market in the country.

In this connection, the ministry will soon constitute a 'special expert committee' which will review all drug formulations in the market and identify drugs which are potentially hazardous and/or of doubtful therapeutic efficacy. Based on the final report of the committee, the ministry will weed out hazardous and irrational drugs from the pharmaceutical market in the country.

According to senior officials in the ministry, a mechanism would be put in place to remove these drugs from the market by the CDSCO at the earliest.

The ministry will also consider banning of a drug already marketed in the country if two or more countries remove the drug from their market due to issues related to safety and efficacy of the drug. “If two or more countries remove a drug from their market on grounds of efficacy and safety, then the continued marketing of the drug in the country will be considered for examination and appropriate action,” officials said.

For continued evaluation of drugs marketed in the country, the CDSCO will be supported by experts who would recommend, from time to time, removal of drugs from the market due to safety and efficacy issues, the officials further added.

The decision to constitute a 'special expert committee' to review all drug formulations in the market was taken at a meeting held by the ministry recently. The meeting was convened to discuss and examine the report of the Prof Ranjit Roy Chaudhury expert committee, which had submitted its report to the government recently, recommending sweeping changes in approval of new drugs, clinical trials and banning of drugs in the country.

Apart from several other sweeping recommendations, the Prof Ranjit Roy committee had also recommended for the setting up of a committee outside of the Drugs Technical Advisory Board (DTAB) to review all the drug formulations and vaccines now in the market and prepare a list of drugs which should be removed from the pharmaceutical market in the country.

The committee, in its report, noted with concern that in India there are unacceptably large number of formulations in the market at present, somewhere between 60000 and 85000, and many of these medicines should not have been allowed to reach the market in the first place.

Government of India accepts Prof. Ranjit Roy Chaudhury panel report on approval of new drugs, clinical trials & banning of drugs

The Union health ministry has accepted the recommendations of the Prof. Ranjit Roy Chaudhury expert committee which had recently submitted its report to the ministry. The committee was constituted by the ministry in February this year to formulate policy and guidelines for approval of new drugs, clinical trials and banning of drugs.

According to senior officials in the ministry, the recommendations of the expert committee were discussed in a meeting with its members recently. During the meeting, clarifications on certain recommendations were obtained from the committee. After the meeting, the ministry in-principle accepted the recommendations of the committee.

Accepting the recommendations of the expert panel for accreditation of ethics committees, investigators and the clinical trial sites, the ministry decided that in order to strengthen the clinical evaluation of new drugs, the clinical trials should be conducted in accredited sites by accredited investigators with the oversight of accredited ethics committees (ECS). As this is a long term measure, in the meantime, Quality Council of India (QCI) will be considered for creating a system for accreditation of investigators, ethics committee and clinical trial sites. Although, the Drugs & Cosmetics Rules, 1945 already provide for registration of ethics committee, accreditation of such committees will be undertaken following a specific procedure.

As this requires amendments in the Drugs & Cosmetics Rules, as an immediate measure, CDSCO would initiate steps relating to the process of accreditation by constituting an expert body of 20-25 experts. The names of experts will be finalized by CDSCO in consultation with Dr. Ranjit Roy Chaudhury, Dr. Y. K. Gupta, Prof. & Head, Dept. of Pharmacology, AIIMS, New Delhi and Dr. Arun Aggarwal, Prof. of ENT, Maulana Azad Medical College, New Delhi, senior officials in the ministry said.

Accepting the recommendations of the committee on the procedure for review of applications of clinical trials and new drugs, officials said that the New Drug Advisory Committees (NDACs) will be renamed as Subject Expert Committees. The members for their meetings will be drawn randomly from a large pool of experts. Applications of clinical trials and new drugs will initially be evaluated by the Subject Expert Committees and their recommendations will be reviewed by the Technical Review Committee (TRC). The TRC will be constituted under DGHS and consisting of experts from each areas i.e. clinical pharmacology, regulatory clinical toxicology/ pathology, medicinal/ pharmaceutical chemistry, pharmacy and immunology including clinicians, basic scientists involved in drug development and subjects specialists (drug indication wise). CDSCO will grant approval of clinical trial and new drugs based on the recommendations of TRC.

Companies eye orphan drugs as new profitable market

Several large pharmaceutical firms, facing expiring patents and lengthy approval processes, are shifting their attention to treatments for rare diseases. These orphan drugs have produced substantial revenue increases in recent years, outpacing more mainstream drugs, and are often given fast-track approval by the FDA. They also are protected against generic competition for seven years, rather than the standard five.

European drug industry moving toward greater transparency

Of 807 clinical trials approved by the European Medicines Agency, 77% disclosed their results within a year of completion or of regulatory approval –- a figure that rose to 89% by January 2013, according to a study by the Association of the British Pharmaceutical Industry. "[W]e fully expect to see the trend towards greater transparency continue on this positive trajectory," said ABPI chief executive Stephen Whitehead. The study appeared in the journal Current Medical Research and Opinion.

South Africa approves compulsory licensing for HIV/AIDS drugs

South Africa will amend its patent laws to permit parallel importing and compulsory licensing of lower-cost HIV/AIDS drugs, reflecting provisions of the international Trade Related Aspects of Intellectual Property Rights agreement. "We are the world capital of HIV/AIDS ... and we have to have the freedom and ability to use the policy space that's been made available to us under TRIPS," said Rob Davies, minister for National Policy on Intellectual Property, Trade and Industry.

Forthcoming Events:

One Day Workshop on

"Clinical Trial: Recent Development in Science and Regulation"

18th November 2013 at 10.00 a.m.

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)

Contact:

Mr. P. K. Mallik

E-mail: ipabengalbranchn@gmail.com

Mob. 09830574612

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

22.11.2013:

Seminar - Institute of Pharmay, Kalyani

23.11.2013:

Cultural Programme, Kolkata

24.11.2013:

DSP, Steel Club-Seminar