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

10th Year Anniversary issue

Volume: 10 ***Number: 26*** ***26th March 2017***

Content

Editorial

It is my proud privilege to pen the editorial at a historical moment – the completion of 10 years of publication of this Drug Information Bulletin. The weekly bulletin started its journey in April 2007, brought out by the Drug Information Centre (DIC), IPA, Bengal Branch and is now a bi weekly bulletin jointly published by Drug Information Centre, IPA, Bengal Branch & Regulatory Affairs Division, IPA. As far as my knowledge, this is the first of its kind of bulletin serving its readers from all spheres of the society like-Pharmacists, Doctors, Nurses, health workers, NGOs, and general public worldwide. It has received reach accolades and great appreciation from most of the readers due to its content and its regular publication. Initially it was started to serve IPA members then receiving request from other professional stake holders, as well as request from other countries the bulletin marched ahead Presently we have readers from different countries all over the world and different strata of society.

Some hospitals and educational institutes are forwarding this bulletin among their faculty members and keeping hard copies in their libraries with our prior permission so that students can read this. A number of Drug Information Centers are reproducing this with our permission both in Govt. and private sector. A few international agencies have extended recognition like-Commonwealth Pharmacists Association (CPA), HIFA, UK etc.

This is a free service to anybody and everybody, and any person / institute interested in drug information, and we have never accepted any donation or advertisement from anybody for this publication to keep our voice unbiased.

This has been possible due to help and co operation from all of our readers and mentors. Hope this bulletin will continue its service to the society with help from all of you in future too! Greetings to all.

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

National Health Policy Published by Govt. of India after 14 years

Ministry of Health and Family Welfare, Government of India has formulated the National Health Policy 2017, after a gap of 14 years, to address the current and emerging challenges in the context of present socio-economic and epidemiological landscapes. The policy informs and prioritizes the role of the Government in shaping health systems in all its dimensions- investment in health, organization and financing of healthcare services, prevention of diseases and promotion of good health through cross-sectoral action, access to technologies, developing human resources, encouraging medical pluralism, building the knowledge base required for better health, financial protection strategies and regulation and progressive assurance for health. Though much emphasis was given on health care providers like Doctors and Nurses, but unfortunately no much importance was given on Pharmacists. Only silver lining is that the term "Pharmacist" appears twice in the 28 page documents, as there was no mention of term "Pharmacist" in the National Health Policy 2002. You all are requested to review the document and give your comments. The detailed document is available at www.cdsco.nic.in

India proposes digital drug-tracking to ensure quality

India's health ministry has proposed that all pharmaceutical manufacturers,wholesalers, retailers participate in a digital "track and trace" system to monitor the quality and safety of the drug supply. Companies would register such information as batch number, quantity, distribution information and expiration dates through a e-platform to be developed by an autonomous agency under the Ministry of Health & Family Welfare, Govt. of West Bengal. Central Govt. has circulated this notification for public consultation. All stakeholders and public at large has requested to forward their suggestions/comments, etc. through e-mail to **epharmacy.drugs-mohfw@gov.in** or send hard copies to Deputy Secretary (Drug Regulation), Ministry of Health and Family Welfare, Room No. 301 D, Nirman Bhavan, New Delhi within a period of 30 days from the day of this notice *i.e.* by or before 15.04.2017. Document is available at www.cdsco.nic.in

Drug Safety Alerts released by PvPI for the month of March 2017

The preliminary analysis of SUSARs from the PvPI database reveals that the following drugs are associated with the risks as given in the table below.

Sl. No.	Suspected Drugs	Indication	Adverse Reactions
1	Deferasirox	Treatment of chronic iron overload in patients with non-transfusion dependent thalassemia (NTDT) syndromes	Osteoporosis
2	Ambroxol	All forms of tracheobronchitis, emphysema with bronchitis pneumoconiosis, chronic inflammatory pulmonary conditions, bronchiectasis, bronchitis with bronchospasm asthma	Lacrimation
3	Lurasidone	Treatment of Patients with Schizophrenia	Thrombocytopenia
4	Eterocoxib	Short term use in acute painful condition	Skin Hyperpigmentation

Health care professionals, Patients/Consumers are advised to closely monitor the possibility of the above adverse events associated with the use of above drugs. If such events are encountered please report to the NCC-PvPI either by filling of Suspected Adverse Drug Reactions Reporting Form/ Medicines Side Effect Reporting Form for Consumer (http://www.ipc.gov.in) or by PvPI Helpline No. 1800-180-3024.

University licenses brain cancer drug to Lin BioScience

Lin BioScience has been granted exclusive worldwide rights to develop and market the University of Sydney's blood-brain barrier permeable, small-molecule drug LBS-002 for brain cancer treatment. Financial details of the deal were not disclosed.
Ref.: Genetic Engineering & Biotechnology News

WHO advised travelers to areas of Brazil should get yellow fever vaccination

The World Health Organization urged travelers to rural areas in the Brazilian states of Rio de Janeiro and Sao Paulo to be inoculated against yellow fever due to an outbreak that has been tied to 137 deaths since December. WHO already urges vaccinations for travelers to the state of Espirito Santo. Health officials have 424 confirmed cases and 933 suspected cases.
Ref.: Reuters

Generic pain drug launched by an Indian company

The AA-rated generic version of Mikart's Hydrocodone Bitartrate and Acetaminophen tablets USP, 5 mg/300 mg, 7.5 mg/300 mg and 10 mg/300 mg has been launched by an Indian firm in the US. The drug is a treatment for moderate to moderately severe pain.
Ref.: Drug Store News

Dr. Scott Gottlieb appointed as US FDA commissioner

Dr. Scott Gottlieb, a former deputy commissioner of the FDA under President George W. Bush and an adviser to GlaxoSmithKline, Bristol-Myers Squibb and Cell Biotherapy, has been nominated by President Donald Trump to become FDA commissioner. Gottlieb, who is seen as an advocate for deregulation, has said he would prioritize getting tougher on unsafe foods and making sure the blood supply is safe, and he is also expected to reduce restrictions on off-label drug uses and speed up approval of generic drugs.
Ref.: Modern Healthcare

Important notice of DCGI for examination of Safety and efficacy of FDCs

Reminder

F. No. 04-01/2013-DC (Misc. 13-PSC)
Directorate General of Health Services
Office of Drugs Controller General (India)
(FDC Division)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated: 01 MAR 2017

NOTICE

Subject: Examination for Safety and Efficacy of Fixed Dose Combinations (FDCs) licensed for manufacture for sale in the country without due approval from office of DCG (I)-regarding.

Reference: 1. This Directorate letter no. 4-01/2013-DC (Misc.-PSC) dated: 15.01.2013.
2. This Directorate Notices dated: 17.06.2016 and 01.09.2016.

This is in continuation to this office earlier letters addressed to individual firms as well as notices dated: 17.06.2016 and 01.09.2016 whereby all concerned stakeholders were requested to submit phase IV trial protocol based on recommendations of Expert Committee. In this regard, it has been observed that most of the companies are yet to submit Phase IV protocol.

It is therefore again requested that all the applicants who have not yet submitted Phase IV trial protocols shall submit the same in accordance with Schedule Y of Drugs and Cosmetics Rules, 1945.

This may be treated as regulatory reminder for further necessary action.

Yours faithfully,

(Dr. G. N. Singh)
Drugs Controller General (India)

Copy to:-

1. JS (R), Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi.
2. All State/UT Drugs Controllers
3. All Zonal/Sub Zonal offices of CDSCO
4. Manufacturing Associations: IDMA/OPPI/IPA/CIPI/FOPE etc.