



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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Regulatory Affairs Division (RAD), IPA

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Editorial

Pharmacovigilance Programme of India (PvPI) has taken a mature shape with more than 200 Adverse Drug Monitoring Centers (AMC) are collecting ADR data regularly and collected about 1.4 lacks of ADR. PvPI is now contributing considerable amount of ADR data to the Uppsala Monitoring Centers (UMC)-a WHO collaborating centre and CDSCO. Recently PvPI has circulated a list of 24 ADRs requesting all concerned to be more vigilant about the drug-ADR combinations mentioned below and report them on priority basis to NCC-PvPI.

3rd version of Pharmacovigilance system in India started in the year of 2010 operating from Indian Pharmacopoeia Commission (IPC) and growing with a steady pace. In order to collect the data from specialized areas two more wings have been developed, which are Haemovigilance Programme (HvPI) and Materiovigilance Programme (MvPI). Haemovigilance Programme (HvPI) started since 10th Dec. 2012 in collaboration with National Institute of Biologicals (NIB) and Materiovigilance programme started since 6th July 2015, Indian Pharmacopoeia Commission (IPC) as National Coordinating Centre & Sree Chitra Tirunal Institute of Medical Sciences & Technology (SCTIMST) will be function as National Collaborating Centre.

Now Adverse Events Following Immunization (AEFI) is also integrated with PvPI. PvPI, CDSCO and Pharmaceutical Industries working to Harmonize PSUR reporting. AMCs have also started in focused therapeutic areas like Anti-tubercular drugs. ADRs are being collected from six centers spread over the country on newly introduced anti-tubercular Drug-Bedaquiline. PvPI is also collaborating with Medical Council of India (MCI), Indian Medical Association (IMA) and pharmaceutical industries for more intensive Pharmacovigilance. It is felt by the experts that the system is working well and will serve the society continuously. On the basis of ADR identified by PvPI, DCGI has taken some steps.



Dr. Subhash C. Mandal
Editor

E mail: subhash.mandaldr@gmail.com

Mob. 9830136291

Drug Alerts: PvPI has issued following drug alerts till date requesting all concerned to be more vigilant about the drug-ADR combinations mentioned below and report them on priority basis to NCC-PvPI.

Sl. No	Suspected Drugs	Indication	Adverse Reactions
1	Phenytoin	Generalized tonic-clonic seizures; partial, seizures; status epilepticus	Angioedema
2	Phenytoin	Generalized tonic-clonic seizures; partial, seizures; status epilepticus	Osteoporosis
3	Nicorandil	Angina Pectoris, Vasodialator	Risk of ulcer complication
4	Olanzapine	Schizophrenia, acute mania episodes in bipolar disorder	Hyponatraemia
5	Crizotinib	Locally advanced or metastatic non-small cell lung cancer (NSCLC) that is anaplastic lymphoma kinase (ALK)	Risk of cardiac failure
6	Roflumilast	Reduce the risk of Chronic Obstructive Pulmonary Diseases exacerbations	Gynecomastia
7	Clozapine	Management of Schizophrenic patients	Neutropenia
8	Disulfiram	Alcohol-Abuse Deterrent	Erythroderma
9	Peginterferon alpha-2a	Chronic active Hepatitis B & C	Vasculitis
10	Piperacillin & Tazobacam	In the treatment of lower RTI/UTI/intra abdominal infections, skin and skin structure infections, bacterial septicaemia polymicrobial infection	Vision abnormal
11	Mometasone Furoate, Topical	Steroid responsive dermatitis , eczema, or atopic dermatitis	Hypertrichosis/Hirsutism, Skin depigmentation
12	Ranibizumab	Neovascular Age-Related Macular Degeneration (AMD), Visual impairment due to Diabetic Macular Edema (DME), visual impairment due to Choroidal Neovascularization (CNV) secondary to Pathologic Myopia (PM).	Myocardial Infarction
13	Amphotericin B	Life threatening fungal infections including histoplasmosis, coccidioidomycosis, paracoccidioidomycosis, blastomycosis, aspergillosis, cryptococcosis, mucormycosis, sporotrichosis and candidiasis; visceral and mucocutaneous leishmaniasis unresponsive to pentavalent antimony compounds; severe meningitis. perioral candidiasis.	Bone Marrow Depression
14	Doxorubicin	Soft tissue and bone sarcomas, acute leukemia, malignant lymphoma, Hodgkin's diseases, breast carcinoma, small cell carcinoma of lungs, AIDS-related Kaposi's sarcoma, multiple myeloma. Gastrointestinal tract carcinoma, bladder cancer,	Photosensitivity Reaction

		ovarian carcinoma, acute myeloblastic leukemia, thyroid carcinoma, neuroblastoma.	
15	Crizotinib	Locally advanced or metastatic Non-Small Cell Lung Cancer (NSCLC) that is Anaplastic Lymphoma Kinase (ALK) – positive.	Pneumonitis, Hepatic Encephalopathy
16	Febuxostat	For treatment of chronic hyperuricemia in conditions where urate deposition has already occurred (including a history, or presence of, tophus and/or gouty arthritis).	Allergic vasculitis
17	Oxcarbamazepine	Monotherapy or adjunctive therapy in the treatment of partial seizure, secondary generalized seizure, substitution for Carbamazepine can be made abruptly with an Oxcarbamazepine – to – Carbamazepine ratio of 300:200.	Syndrome of Inappropriate Antidiuretic Hormone secretion (SIADH).
18	Artemether & Lumefantrine	For treatment of uncomplicated falciparum malaria, mixed infections of falciparum and Chloroquine resistant vivax malaria.	Stevens- Johnson syndrome/Toxic epidermal necrolysis
19	Cefixime	Otitis media, respiratory tract infections, uncomplicated UTIs, effective against infections caused by Enterobacteriaceae, H.influenza species.	Acute generalised exanthematous pustulosis (AGEP)
20	Hepatitis B immune globulin (human)	Active immunisation against Hepatitis B virus (HBV) infection in subjects considered at risk of exposure to HBV-positive material.	Encephalopathy
21	Cefotaxime	Infections due to sensitive gram-positive and gram-negative bacteria such as bacteraemia, cellulitis, Intra-abdominal infections, gonorrhoea, bone or joint infections, skin and skin structure infections, urinary tract infections, septicaemias, surgical prophylaxis, endometritis, life threatening resistant/hospital acquired infections, infections in immune-compromised patients, Haemophilus epiglottitis and meningitis.	Anaphylactic Shock.
22	Lacosamide	As an adjunctive treatment of partial onset seizures in patients > 17 years of age.	Red Man Syndrome
23	Dimethyl fumarate	For Relapsing remitting multiple sclerosis.	Osteonecrosis
24	Sodium citrate/ Diphenhydramine hydrochloride/ Ammonium chloride	For Symptomatic treatment of cough.	Myocardial

Final draft of national drugs survey conducted in 2015 submitted to health ministry

Aimed at getting an authentic scenario of spurious and NSQ drugs in the Indian healthcare system, the much awaited national spurious drugs survey has finally been submitted to the Union health ministry for further approval and release.

Samples during the pan-India exercise were collected from 665 of the total 676 districts of the country based on a statistical design encompassing all the retail drug stores including government medical stores, CHCs and PHCs in collaboration with Indian Statistical Institute (ISI), Kolkata and Hyderabad and National Sample Survey Organisation (NSSO).

The draft report submitted is the culmination of a pan-India sampling exercise done by the National Institute of Biologicals (NIB) of nearly 48, 000 samples and chemical analysis involving 10 drug testing labs from across the country.

Samples were being sent online through a specialised AKS software to Central Drug Testing Labs (CDTL) in Chandigarh, Mumbai, Hyderabad, Chennai, Kolkata and Guwahati for analysis and final report. Other State Drugs Testing Labs at Vadodara, Karnataka and at IPC, Ghaziabad are also a part of testing and analysis.

The Union health ministry had entrusted the job of National Drugs Survey in July 28, 2014 to Noida based National Institute of Biologicals to accomplish the study in a scientific manner as per Indian pharmacopoeia and other pharmacopoeias.

Done at an estimated cost of Rs. 8.5 crore, the survey is the first of its kind study to have concluded complete testing of NSQ and spurious drugs. Dr Surinder Singh, Director, NIB is the chairman of the committee which conducted the survey.

Aimed at identifying geographical areas where spurious drugs are available, around 1000 drug inspectors from across the country were trained for the pan-India initiative.

The National Sample Survey Office (NSSO) had asked the state governments to provide information to arrive at a statistical design for the survey like information such as the number of retail outlets (district-wise), information regarding the maximum prescription of drugs under each of the 15 categories including their trade name district wise, number of civil hospital stores (district-wise), number of central medical store (state-wise) and number of Central Government Health Scheme (CGHS) dispensaries throughout the country.

In order to facilitate effective sampling of drugs by the drugs inspectors, all the 224 molecules covering 15 therapeutic drug categories were assigned a unique sequence in the format developed through a statistical design which ensured that the drug inspector can pick up samples only on the basis of the statistical design and not on his own will.

Source: Pharmabiz

Nonprofit funds 14 pharma and medtech projects in Australia

MTPConnect, an Australian nonprofit organization, said it will invest \$7.4 million in 14 pharmaceutical, medtech and biotech projects in the next two years, with industry partners contributing an additional \$32 million. Among the projects being funded is a national consortium for research and training in pharmaceuticals and medical technology.

Ref. [BioSpectrum Asia](#)

NPPA can cap drug prices without fixed rules, India's Supreme Court says

India's Supreme Court ruled last week that the country's National Pharmaceutical Pricing Authority can impose a ceiling on drug prices even before the rules are fixed. The court was ruling on cases related to drugs from Dr. Reddy's Laboratories and Cipla.

Ref. [The Economic Times \(India\)](#)

FDA updates list of drugs removed from market

The FDA revised its ruling to update the list of drug products that have been removed or

withdrawn from the market due to issues regarding safety and effectiveness, stating that drugs appearing on the list may not be compounded. The rule adds 24 entries to the list, revises the title and introduction, and modifies the description of one entry on the list.

Ref. FederalRegister.gov

Forthcoming Events:

55th National Pharmacy Week Celebration

by
Indian Pharmaceutical Association, Bengal
Branch
20th -27th November 2016
Tentative Programme

- 20.11.2016:** Inauguration
Venue: Meghnad Saha Auditorium, Central Glass & Ceramic Research Institute
Time; 10.00 am
- 21.11.2016:** Pharma Rally at Uluberia, Howrah
- 23.11.2016:** Seminar at Institute of Pharmacy, Kalyani, Nadia on NPW Theme.
- 24.11.2016:** Blood Donation Camp, Institute of Pharmacy, Kalyani, Nadia
- 25.11.2016:** Students' Day at NSHM Knowledge Campus, Kolkata Group of Institute
Seminar on "Diabetes and its control over life" at Jakir Hossain Institute of Pharmacy, iapur, Murshidabad.
- 26.11.2016:** Cultural Programme
Hospital Pharmacy Day at NRS Medical College & Hospital, Kolkata
Workshop on "New Federation Regulation by PCI" at CIPT, Uluberia
- 27.11.2016:** National Workshop on "Pharmacists for a Healthy India" against registration fees as under:
IPA Members: Rs. 400/-; Non Members : Rs. 500/-; Student Members of IPA : Rs. 300/-
Student Non-member : Rs. 400/-
Seminar at D.S.P. Main Hospital Conference Hall, Durgapur.

National workshop on

"Pharmacists for a Healthy India"

27th November 2016

**Indian Institute of Chemical Engineers
(Dr. H. L. Roy Building), Jadavpur University
188 Raja S.C. Mullick Road, Kolkata-700032**

Organized by:

**Indian Pharmaceutical Association
Bengal Branch**

Telefax: +91 33 24612776,

Web: [http:// www.ipabengal.org](http://www.ipabengal.org)

E-Mail: ipabengal@gmail.com

Abstract Submission for Poster Presentation:

Last date: 11.11.2016



The poster for the 68th Indian Pharmaceutical Congress 2016 features a central image of a beach with waves and a clock tower in the background. The text includes the IPC logo, the event title, and a list of activities. A circular graphic on the left lists the following items:

- First Mega Pharma Event in AP
- Plenary Lecturers and Symposia by Eminent Scientists
- Pharma Expo & B2B Events
- Placement Conclave For Students
- Supported by : IPA- Visakhapatnam Local Branch

Visit us at www.68thipc.com

Organised by: Indian Pharmaceutical Congress Association, Bangalore

Host: Indian Pharmaceutical Association, Mumbai

Venue: College of Pharmaceutical Sciences, Andhra University, Visakhapatnam

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