



# Clinical Pharmacy

A Newsletter of Drug and Prescribing Information

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## ADVERSE DRUG REACTION REPORTS: JAN APR 2017

A total of 652 Adverse Drug Reactions (ADRs) were reported or detected by the Department of Clinical Pharmacy during January to April 2017. The following are some of the suspected ADRs that were either reported to or detected by the Department of Clinical Pharmacy. In most of the cases there was a change in drug therapy e.g. cessation of suspected drug or reduction in dose, and/or either specific or symptomatic treatment for the suspected ADR.

Acenocoumarol	.....	Epistaxis
Amitriptyline	.....	Asthenia
Atenolol	.....	Chronic Plaque Psoriasis
Carbimazole	.....	Cholestatic Hepatitis
Cerebro protein hydrolysate	.....	Anaphylactic Shock
Clobazam	.....	Sialorrhoea
Naproxen	.....	Mouth Ulceration
Nevirapine	.....	Lactic Acidosis
Nevirapine	.....	Stevens Johnson Syndrome
Phenytoin	.....	Ataxia
Risperidone	.....	Dystonia
Spironolactone	.....	Gynaecomastia
Sulfasalazine	.....	DRESS Syndrome
Valproate Sodium	.....	Hyperammonaemia
Zidovudine + Lamivudine + Nevirapine	.....	Cyanosis

### Atenolol induced Chronic Plaque Psoriasis:

Several theories have been proposed regarding the pathogenesis of beta blocker-induced psoriasis. These include a delayed type hypersensitivity reaction, immunological mechanisms including impaired lymphocyte transformation, or alterations in the cyclic adenosine monophosphate (cAMP) pathway. This reaction can be persistent and resistant to therapy until the withdrawal of the drug. Conventional topical and systemic therapeutic agents can be used to treat the condition after the dechallenge of the offending drug.

### Phenytoin induced Ataxia:

Phenytoin induced ataxia is a dose related ADR, which occurs when the plasma levels reach 30 ml/dl and may show great diversity among the patients. It is important to notice that there can be a chance of toxicity with the patients who experience an Ataxia. It is necessary to monitor the dosing, plasma concentrations regularly and identify the adherence issues in patients on Phenytoin to prevent ADRs like ataxia, Nystagmus and drowsiness.

### Nevirapine induced Lactic Acidosis:

The proposed mechanism for the development lactic acidosis is the inhibition of mitochondrial DNA polymerase- $\gamma$ , leading to depletion of mtDNA and diminished capacity of the oxidative phosphorylation system. Patients on long-term therapy with antiretroviral therapy who complain of non specific symptoms such as loss of appetite, fatigue, nausea, weight loss must be tested for levels of venous lactate so as to detect symptomatic hyperlactatemia at an early stage. So that potentially fatal complication such as lactic acidosis could be prevented by prompt withdrawal of the drug and timely management.

We encourage you to report all suspected adverse drug reactions to Department of Clinical Pharmacy. Adverse drug reaction reporting forms are available at all nursing stations. Alternatively you may call Department of Clinical Pharmacy on 2335555 Extn. 5577 or SMS to 07411137840 (Format: ADR/ IP or OP Number/ Name of the patient/ Ward)

## DRUGS APPROVED BY US FDA : JAN - APR 2017

DRUG	BRAND	USE
<b>Dermatology</b>		
Avelumab	Bavencio	For the treatment of Merkel Cell Carcinoma
Dupilumab	Dupixent	For the treatment of atopic dermatitis
<b>Endocrinology</b>		
Etelcalcetide	Parsabiv	For the treatment of secondary hyperparathyroidism in adults with chronic kidney disease on hemodialysis
<b>Gastroenterology</b>		
Naldemedine	Symproic	For the treatment of opioid-induced constipation
<b>Genetic Disease</b>		
Cerliponasealfa	Brineura	For the treatment of late infantile neuronal ceroidlipofuscinosis type 2
<b>Hematology</b>		
Midostaurin	Rydapt	For the treatment of FLT3 positive acute myeloid leukemia and mastocytosis
<b>Immunology</b>		
Ocrelizumab	Ocrevus	For the treatment of multiple sclerosis
<b>Musculoskeletal</b>		
Cerliponasealfa	Brineura	For the treatment of late infantile neuronal ceroidlipofuscinosis type 2
<b>Nephrology</b>		
Etelcalcetide	Parsabiv	For the treatment of secondary hyperparathyroidism in adults with chronic kidney disease on hemodialysis
<b>Neurology</b>		
Cerliponasealfa	Brineura	For the treatment of late infantile neuronal ceroidlipofuscinosis type 2
<b>Obstetrics/Gynecology</b>		
Ribociclib	Kisqali	For the treatment of breast cancer
<b>Oncology</b>		
Niraparib	Zejula	For the treatment of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer
Telotristat ethyl	Xermelo	For the treatment of carcinoid syndrome diarrhea
<b>Pediatrics/Neonatology</b>		
Cerliponasealfa	Brineura	For the treatment of late infantile neuronal ceroidlipofuscinosis type 2

*Reference:* <https://www.centerwatch.com/drug-information/fda-approved-drugs/>

## DRUGS APPROVED BY CDSCO, INDIA : JAN - APR 2017

DRUG	STRENGTH	INDICATION
Dexlansoprazole Delayed Release Capsule	30/60mg	For the treatment of i) Healing of all grades of erosive esophagitis (EE). ii) Maintaining healing of EE and relief of heartburn. iii) Treating heartburn associated with symptomatic non-erosive gastroesophageal reflux disease (GERD).
Carfilzomib Sterile Lyophilized Powder for Injection	60mg/vial (50ml vial)	Relapsed or refractory multiple myeloma  <ul style="list-style-type: none"> <li>Carfilzomib for injection is indicated in combination with dexamethasone or with lenalidomide plus dexamethasone for the treatment of patients with relapsed or refractory multiple myeloma who have received one to three lines of therapy.</li> <li>Carfilzomib for injection is indicated as a single agent for the treatment of patients with relapsed or refractory multiple myeloma who have received one or more lines of therapy.</li> </ul>
Dabrafenib Capsules (DabrafenibMesylate)	50mg/75mg	As a single agent for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an appropriate test. In combination with Trametinib for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an appropriate test.
Trametinib Tablets (Trametinib Dimethyl Sulfoxide)	0.5mg/2mg	As a monotherapy and in combination with Dabrafenib for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an appropriate test.

*Reference:* <http://www.cdsc0.nic.in/forms/list.aspx?lid=2034&Id=11>

## Long Term Aspirin May Cut Risk for Cancer Death

According to a new observational study with a median follow up of 32 years concluded that the regular use of aspirin can reduce relative risk for death from any cause and death from cancer. Overall mortality risk was 7% lower for women and 11% lower for men, who regularly used aspirin compared with non-regular aspirin users. And cancer mortality risk was 7% lower for women and 15% lower for men who regularly used aspirin.

The reduction in the risk of cancer death may seem modest

but the effect sizes comparable to the increased in the risk of cancer death associated with obesity. Although aspirin reducing mortality risk with cancers like colorectal cancer, but it carries risk of gastro intestinal (GI) bleeding and haemorrhagic stroke.

**Reference :** American Association for Cancer Research (AACR) 2017 annual meeting coverage. Available from <http://www.medscape.com/viewarticle/878305>.

## Amputation Warning With SGLT2 Inhibitors Must Be on Label

Pharmacovigilance Risk Assessment Committee (PRAC) of European Medicines Agency (EMA) issued a warning on 12th February 2017, to include the risk for lower limb amputation in the prescribing information of the sodium glucose cotransporter 2 (SGLT2) inhibitors for type 2 diabetes. The warning was based on the data from two ongoing clinical trials with canagliflozin patients at high risk for cardiovascular events, Canagliflozin Cardiovascular Assessment Study (CANVAS) and a related study of renal end points, CANVAS-R.

The EMA had announced its investigation into the possible lower-limb amputation risk with canagliflozin in April 2016 and expanded its investigation to include all SGLT2 inhibitors that is, dapagliflozin and empagliflozin as well in July 2016. The mechanism by which SGLT2 inhibitors increasing the risk of amputation is still not understood. In a 4.5-year interim analysis of CANVAS, the independent

monitoring committee for the trial found that the rate of amputations per every 1000 patients was equivalent to seven for 100 mg/day and five for 300 mg/day of canagliflozin compared with three per 1000 patients taking placebo. Most of the amputations were of toes.

For canagliflozin specifically, lower-limb amputation risk would be listed as an "uncommon side effect," occurring in between one and 10 per 1000 patients. Clinicians are advised to consider stopping treatment if patients develop significant foot complications, such as infection or ulcers. In the United States, the Food and Drug Administration (FDA) also issued a safety alert in May 2016 for canagliflozin based on the same data, but not other SGLT2 inhibitors

**Reference:** EMA: Amputation Warning With SGLT2 Inhibitors Must Be on Label [www.medscape.com/viewarticle/875649](http://www.medscape.com/viewarticle/875649).

## DEPARTMENT ACTIVITIES

### 3rd Asia Pacific Pharmacovigilance Training Course

JSS University in collaboration with Uppsala Monitoring Centre (UMC), the World Health Organisation Collaborating Centre for International Drug Monitoring in Sweden, conducted Asia Pacific Pharmacovigilance Training Course for the third consecutive year from 16-27 January 2017 at JSS College of Pharmacy, Mysuru. The course aims at building pharmacovigilance capacities amongst healthcare professionals, providing solid practical foundations for those working in drug safety and updates for experienced staff in the Asia Pacific region and beyond.

The inaugural event of the training program was held on 16th

January 2017 at 9am in the seminar Hall of JSS College of Pharmacy, Mysuru. Dr. G. Parthasarathi, Principal, JSS College of Pharmacy, Mysuru & Dean, Faculty of Pharmacy, JSS University, Mysuru, Mr. Sten Olsson, WHO program expert, UMC, Sweden, Dr. B. Suresh, Vice Chancellor, JSS University, Mysuru & President, Pharmacy Council of India and Mr. Micheal Deats from Essential Medicines Division of WHO, Geneva were present during the inaugural function.



From left to right: Dr. B. Suresh, Mr. Sten Olsson, Mr. Micheal Deats & Dr. G. Parthasarathi during inauguration



Participants with course faculty

The two-week course was taught by field experts from JSS College of Pharmacy, Mysuru and UMC, Sweden as well as by external speakers from India and abroad. Twenty six

internationally known experts from Sweden, Switzerland, Australia, The Netherlands, Scotland, Morocco, Kenya, Bhutan and India were participated in the program as speakers and trainers. The covered topics ranged from health impacts of low quality medicines to effects of inappropriate use of medicines and adverse drug and vaccine reactions. This course has drawn 28 attendees from national regulatory authorities, pharmaceutical companies, academia, contract research organisations, and the healthcare sector in 13 countries in Asia and other parts of the world.

All the participants unanimously told that this training course helped them to gain more knowledge on spontaneous reporting of adverse events, data management & analysis

tools, signal detection, causality assessment, communications in pharmacovigilance, pharmacovigilance methods, pharmacoepidemiology and regulatory aspects of pharmacovigilance and vaccine pharmacovigilance. The knowledge and skills gained will help them to initiate or further strengthen the pharmacovigilance activities in their respective country or organization. Also the interactions with resource persons from different parts of the world can be utilized for future international collaboration and building a global pharmacovigilance network which will help them to improve the safe and quality use of medicine both at regional and global level.

### Achievements of the Department Staffs and Students

**Mrs. Shilpa Palaksha**, received 'Best Poster award' for the presentation entitled 'Assessing the factors that influence the selection of inhaler device -Patient Perspective' during Second International Conference on Clinical Pharmacy-CPCON 2017 held on 20<sup>th</sup> & 21<sup>st</sup> January 2017 at Manipal College of Pharmaceutical Sciences, Manipal



*Mrs. Shilpa Palaksha with Best poster Award*

**Mr. Himanshu Patel** was selected as Member of International Society of Oncology Pharmacy Practitioners (ISOPP) Advocacy Task Force by ISOPP. He has been nominated as a representative to lead project on preparing essential cancer medicine list for country of Kazakhstan. This project is designed and executed jointly by Union for International Cancer Control (UICC) and World Health Organization (WHO), Geneva with Government of Kazakhstan.

**Mr. Sri Harsha Chalasani** received a Best Poster Award for the research paper titled "Assessment of Medication Errors in the Intensive Care Unit in a developing country's Tertiary Care Teaching Hospital" presented in 7<sup>th</sup> Pharmaceutical Care Conference held at Al-Bustan Palace, Muscat, Sultanate of Oman on 22<sup>nd</sup> & 23<sup>rd</sup> February 2017.

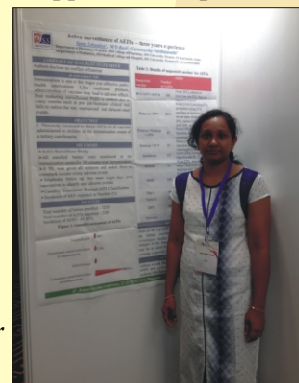
### International Visits

**Mr. Himanshu Patel**, Assistant Professor presented "Oncology Pharmacy Practice in India and at JSSU at Global Oncology Pharmacy Summit organized by International Society of Oncology Pharmacy Practitioners (ISOPP) at Budapest, Hungary held on 24-25 April 2017. This summit was attended by 22 invited oncology pharmacy leaders from 16 different countries. During this summit, he also acted as member of ISOPP oncology pharmacy practice standards review committee and ISOPP advocacy task force. Mr. Himanshu Patel received Euro 1900 from ISOPP to support his attendance at summit.



*Mr. Himanshu with oncology pharmacy practice standard committee members*

**Mrs. Juny Sebastian**, Lecturer, Dept. of Pharmacy Practice attended the 6<sup>th</sup> Asian Vaccine Conference (ASVAC 2017) held during 27<sup>th</sup> to 29<sup>th</sup> of April 2017 at Concorde Hotel, Singapore. ASVAC is an official conference of Immunization Partners for Asia Pacific (IPAP), which will be conducted once in two years. She also attended rota council advocacy and vaccinology masterclass preconference workshops. She presented two papers on "Active surveillance of AEFIs: three years experience" and "Assessment of quality and safe use of vaccines- A pilot study" during the conference. She received a travel grant from JSS University to support her expenses to participate in ASVAC 2017



*Ms. Juny during Poster presentation*

## Guest Lectures

Name and details of the Expert	Date	Lecture Topic
<b>Sten Olsson</b> Uppsala Monitoring Centre, Sweden	16-1-2017	1. Importance of safety monitoring / Why pharmacovigilance 2. Pharmacovigilance global perspective - WHO international drug monitoring programme
	18-1-2017	Pharmacovigilance in Public Health Programmes
	19-1-2017	Pharmacovigilance Methods
	23-1-2017	1. Information resources in Pharmacovigilance 2. PV capacity building and organization on the regional and national level
	24-1-2017	1. Identification of new adverse drug reactions 2. Pharmacovigilance Indicators
	26-1-2017	Recent advances/changes in Pharmacovigilance regulatory requirements
<b>Birgitta Grundmark</b> Uppsala Monitoring Centre, Sweden	16-1-2017	Clinical Diagnosis of ADRs
	20-1-2017	Risk, risk perception and benefit-risk balance & Risk management
<b>Michael Deats</b> World Health Organization, Switzerland	17-1-2017	Wider scope of Pharmacovigilance Substandard and falsified medical products-A global view from WHO
<b>SaadiSkalli</b> Moroccan Poison Control and Pharmacovigilance Centre, Morocco	17-1-2017	Wider Scope of Pharmacovigilance – Medication Errors
<b>AlpanaMair</b> The Scottish Government, United Kingdom	17-1-2017	Wider Scope of Pharmacovigilance: Adverse Drug Interaction & Antimicrobial resistance
<b>Jennifer Wall</b> Uppsala Monitoring Centre, Sweden	18-1-2017	1. Spontaneous ADR reporting system 2. Developing a positive ADR reporting culture 3. How to collect ADR information
<b>DelianaAboka</b> Uppsala Monitoring Centre, Sweden	18-1-2017	ICSR management tools
	19-1-2017	Vigilyze introduction and demonstration
<b>Alexandra Hoegberg</b> Uppsala Monitoring Centre, Sweden	25-1-2017	Communication in pharmacovigilance
<b>AnandHarugeri</b> Quintiles, India	26-1-2017	Establishment of drug safety department in a Pharmaceutical industry
<b>Dr. Amruthesh Shivachar</b> , Associate Professor of Texas Southern University, Houston	17- 3-2017	Team-Based Learning (TBL) in Pharmacy Education
		Introduction to Epilepsy/Antiepileptic Drugs (AEDs)
<b>Dr. Chris Alderman</b> , Associate Professor, University of South Australia, Adelaide	31-3-2017	Psychotherapy outcomes research in psychiatric practice
	01-4-2017	Management of Psychiatric Illnesses

## Visit of Students from OMAN Medical College

As a part of MOU between JSS University, Mysuru and Oman Medical College, Muscat, five students from Oman Medical College (OMC), Muscat, arrived at JSS College of Pharmacy, Mysuru on student exchange program, on 6<sup>th</sup> February 2017. The experiential program was to expose the students to an international rotation focused on public health and infectious diseases that are common in developing countries. The length of the training was for a period of 5 weeks which commenced from 6<sup>th</sup> February to 25<sup>th</sup> March 2017. They were initially posted to pharmacy to learn about Hospital Pharmacy & Inventory Control. They were introduced to various clinical Pharmacy activities of the department.

During their rotation, they were posted to Medicine department for a period of one week each to learn about most common diseases and clinical pharmacy activities. They visited various departments like Nephrology, Paediatrics and Psychiatry. They had taken up various



*OMC Students with Department staff*

cases from the departments and discussed them with their respective facilitators. They had presented cases selected from their area of interest. They attended the case presentations with Interns. They were posted to Asha Kirana Hospital and Bharath Hospital and Institute of Oncology for a period of one week to learn about infectious diseases.

**The Drug & Poison Information Service :** Our Department can help you with any questions you might have on the use of medicines or the management of poisoned patients. We can also assist you with any medication related problems you face in your daily practice. The services are made available on all working days and it is provided free of cost. We request you to avail the drug and poison information services. : **Toll free - 1800-425-0207; 0821-2335577; Extn. 5577;**  
**E-mail:** dic.jsscp@jssuni.edu.in; pic.jsscp@jssuni.edu.in; **Website:** picjsscp.jssuni.edu.in

**Your suggestions are welcome. Please send your comments/suggestions to the editors at: dic.jsscp@jssuni.edu.in**

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