

Clinical Pharmacy

A Newsletter of Drug and Prescribing Information

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ADVERSE DRUG REACTION REPORTS : MAY – AUG 2019

A total of 572 Adverse Drug Reactions (ADRs) were reported or detected by the Department of Clinical Pharmacy during May to August 2019. 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.

DRUG(S)	REACTION
Amisulpride	Dystonia
Atazanavir	Lipodystrophy
Atorvastatin	Steven Johnson Syndrome
Cefpodoxime	Toxic Epidermal Necrolysis
Febuxostat	Steven Johnson Syndrome
Fosphenytoin	Nystagmus
Irinotecan	Hyperbilirubinemia
Linezolid	Hypersensitivity Reaction
Metoprolol	Psoriasis
Netilmicin	Tetany
Oxaliplatin	Paresthesia
Phenytoin	DRESS Syndrome
Rivaroxaban	Leucocytoclastic Vasculitis
Teicoplanin	Toxic Epidermal Necrolysis
Vancomycin	Red Man Syndrome

Netilmicin induced Tetany

Netilmicin induced tetany is a rare reaction which is characterized by spasm of hands and feet. Tetany might occur due to Netilmicin induced hypocalcaemia. This reaction might develop within 3 to 5 days after initiation of the treatment. The reaction might subside after discontinuation of the drug and treated with calcium supplements.

Oxaliplatin induced Paresthesia

Oxaliplatin induced paresthesia is an acute, rapidly reversible neurosensory toxicity. Paresthesia of hands, feet and peroral region may occur shortly after infusion. These symptoms are usually transient and may increase in both duration and severity with repeated administration. Prophylactic therapy with carbamazepine and glutathione may be useful to prevent this reaction.

Rivaroxaban induced Leucocytoclastic Vasculitis

Rivaroxaban induced leucocytoclastic vasculitis is a rare reaction and is associated with the deposition of the immune complex in small vessels that brings about loss of vessel wall integrity. The exact mechanism is unknown however the underlying cause includes connective tissue diseases, systemic diseases, hematologic or solid organ malignancies. The symptoms may occur within 7-10 days after initiation of the medication. Management includes cessation of the causative drug. Systemic therapies such as corticosteroids, dapsone and other immunosuppressive medications are used for managing serious and refractory conditions.

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 9035664802 (Format: ADR / IP or OP Number/ Name of the patient/ Ward)

DRUGS APPROVED BY US FDA

The following are the drugs that are approved by the US Food and Drug Administration (FDA) during the period May to August 2019.

DRUG	BRAND	INDICATION
Cardiology/Vascular Diseases		
Tafamidis and Tafamidis meglumine	Vyndamax and Vyndaqel	Cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis
Dental and Oral Health		
Apremilast	Otezla	Oral ulcers associated with Behçet's Disease
Gastroenterology		
Pembrolizumab Imipenem, cilastatin, and relebactam	Keytruda Recarbrio	Recurrent esophageal cancer with PD-L1 expressing tumors Complicated intra-abdominal and urinary tract infections
Genetic Disease and Musculoskeletal		
Onasemnogene abeparvovecxiol	Zolgensma	Pediatrics <2 years of age with spinal muscular atrophy with bi-allelic mutations in the SMN1 gene
Hematology		
Fedratinib Polatuzumab vedotin-piiq Selinexor Venetoclax and Obinutuzumab	Inrebic Polivy Xpovio Venclexta and Gazyva	Myelofibrosis Diffuse large B-cell lymphoma Relapsed or refractory multiple myeloma in adults Chronic lymphocytic leukemia or small lymphocytic lymphoma
Hepatology (Liver, Pancreatic, Gall Bladder)		
Ramucirumab	Cyramza	Hepatocellular carcinoma with elevated alpha-fetoprotein (AFP)
Immunology and Musculoskeletal		
Amifampridine Apremilast	Ruzurgi Otezla	Lambert-Eaton myasthenic syndrome in pediatrics Oral ulcers associated with Behçet's Disease
Infections and Infectious Diseases		
Dengue Tetravalent Vaccine, Live Ruxolitinib TB Alliance Imipenem, cilastatin, and relebactam Lefamulin	Dengvaxia Jakafi Pretomanid Recarbrio Xenleta	Dengue disease Steroid-refractory acute graft-versus-host disease in adults and pediatrics >12 years Adults with drug resistant tuberculosis Complicated intra-abdominal and urinary tract infections Community acquired bacterial pneumonia,
Musculoskeletal		
Upadacitinib	Rinvoq	Rheumatoid arthritis
Nephrology and Oncology		
Avelumab Axitinib	Bavencio Inlyta	First line treatment of advanced renal cell carcinoma
Neurology		
Pitolisant Midazolam Amifampridine	Wakix Nayzilam Ruzurgi	Excessive daytime sleepiness in adults with narcolepsy Intermittent, stereotypic episodes of frequent seizure activity Lambert-Eaton myasthenic syndrome in pediatrics

Obstetrics/Gynecology		
Alpelisib	Piqray	HR+, HER2-negative, PIK3CA-mutated advanced or metastatic breast cancer
Bremelanotide injection	Vyleesi	Premenopausal women with acquired, generalized hypoactive sexual desire disorder
Oncology		
Fedratinib	Inrebic	Myelofibrosis
Ramucirumab	Cyramza	Hepatocellular carcinoma with elevated alpha-fetoprotein (AFP)
Pembrolizumab	Keytruda	Recurrent esophageal cancer with PD-L1 expressing tumors
Pembrolizumab	Keytruda	Metastatic small cell lung cancer and stage III non-small cell lung cancer
Darolutamide	Nubeqa	Non-metastatic castration-resistant prostate cancer
Alpelisib	Piqray	HR+, HER2-negative, PIK3CA-mutated advanced or metastatic breast cancer
Polatuzumab vedotin-piiq	Polivy	Diffuse large B-cell lymphoma
Entrectinib	Rozlytrek	ROS1-positive non-small cell lung cancer and NTRK Gene Fusion-Positive Solid Tumors
Pexidartinib	Turalio	Symptomatic tenosynovial giant cell tumor
Venetoclax and Obinutuzumab	Venclexta and Gazyva	Chronic lymphocytic leukemia or small lymphocytic lymphoma
Selinexor	Xpovio	Adults with relapsed or refractory multiple myeloma
Otolaryngology (Ear, Nose, Throat)		
Dupilumab and Pembrolizumab	Dupixent and Keytruda	Chronic rhinosinusitis with nasal polyposis in adults Recurrent esophageal cancer with PD-L1 expressing tumors
Pediatrics/Neonatology		
Pembrolizumab	Keytruda	Recurrent esophageal cancer with PD-L1 expressing tumors
Midazolam	Nayzilam	Intermittent, stereotypic episodes of frequent seizure activity
Amifampridine	Ruzurgi	Lambert-Eaton myasthenic syndrome in pediatrics
Onasemnogene abeparvovecxioi	Zolgensma	Pediatrics <2 years of age with spinal muscular atrophy with bi-allelic mutations in the SMN1 gene
Pulmonary/Respiratory Diseases		
Pembrolizumab	Keytruda	Metastatic small cell lung cancer
Entrectinib	Rozlytrek	ROS1-positive non-small cell lung cancer and NTRK Gene Fusion-Positive Solid Tumors
Lefamulin	Xenleta	Community acquired bacterial pneumonia
Rare Diseases and Disorders		
Apremilast	Otezla	Adults with oral ulcers associated with Behçet's Disease
Rheumatology		
Upadacitinib	Rinvoq	Rheumatoid arthritis
Urology		
Darolutamide	Nubeqa	Non-metastatic castration-resistant prostate cancer

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

DRUGS APPROVED BY CDSCO, INDIA

The following are the drugs that are approved by the Central Drugs Standard Control Organization (CDSCO) during the period May to August 2019.

NAME OF THE DRUG	INDICATION
Concentrate of Proteolytic enzyme enriched in Bromelain topical gel	Indicated for removal of eschar in adults with deep partial and full thickness thermal burns
Menotrophin injection 600 IU/ml, 1 ml & 2 ml multi dose vial (Highly purified)	Menotropin is indicated for the treatment of female and male infertility in the following conditions: <ul style="list-style-type: none"> ● Anovulation, including Polycystic Ovarian Disease (PCOD), in women who have been unresponsive to the treatment with Clomiphene citrate ● Women undergoing controlled ovarian hyperstimulation to induce the development of multiple follicles for Assisted Reproductive Technologies (ART) ● Hypogonadotropic hypogonadism in men
Rifapentine 150mg film coated tablet	For the treatment of latent tuberculosis infection caused by Mycobacterium tuberculosis in adults and children 2 years and older who are at high risk of progression to tuberculosis disease (including those in close contact with active tuberculosis patients, recent conversion to a positive tuberculin skin test, HIV-infected patients, or those with pulmonary fibrosis on radiograph).
FDC of Bictegravir, Emtricitabine and Tenofovir alafenamide 50mg/200mg/25mg tablets	For the treatment of human immunodeficiency virus type 1 (HIV -1) infection in adults who have no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically suppressed (HIV -1 RNA less than 50 copies per ml) on a stable antiretroviral regimen for at least 3 month with no history of treatment failure and no known substitutions associated with resistance to Bictegravir, Emtricitabine and Tenofovir alafenamide.
Levomilnacipran ER capsules 20mg/40mg/80mg/120mg	For treatment of major depressive disorder

Reference : https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NDgzMQ==

Long-term Safety, Tolerability of Belimumab for Systemic Lupus Erythematosus

A human IgG1- monoclonal antibody, belimumab inhibits the survival of B cells, including auto reactive B cells, and reduces their differentiation into Immunoglobulin-producing plasma cells. It is supplied as a solution for intravenous infusion and specifically indicated for the treatment of adult patients with active, autoantibody-positive, Systemic Lupus Erythematosus (SLE) who are receiving standard therapy as well as pediatric SLE patients aged ≥ 5 years. Belimumab for SLE has demonstrated a stable safety profile over 8 years of follow-up, with no new safety signal and minimal organ damage progression, according to data from an extension study involving non-American patients who completed the phase III BLISS*-52 or BLISS-76 trials. In this multicentre, long term extension study, patients received intravenous Belimumab (10mg/kg) every 4 weeks plus standard therapy. Adverse Events (AE), were assessed monthly and safety-associated laboratory parameters were assessed at regular intervals. Organ damage was assessed every 48 weeks.

A total of 738 patients (mean age, 37.2 years; 94.6 percent female; 29.2 percent Asian) entered the extension study and 99.5% (n=735) received one or more doses Belimumab . Annual incidence of AEs, including severe AEs, remained

stable or declined over time. Sixty-nine (9.4%) patients experienced an AE resulting in discontinuation of Belimumab or withdrawal from the study. The top five AEs were headache (n=205; 27.9%), nasopharyngitis (n=155; 21.1%), diarrhoea (n=143; 19.5%), arthralgia (n=136; 18.5%) and influenza (n=134; 18.2%). Eleven deaths occurred including one (cardiogenic shock) considered possibly related to Belimumab. Laboratory parameters generally remained stable. The mean Systemic Lupus International Collaborating Clinics/American College of Rheumatology (SLICC/ACR) Damage Index score was 0.6 at baseline and remained stable. In the eighth year, 57 of 65 patients (87.7 percent) showed no change in SLICC/ACR Damage Index score, indicating low organ damage accrual. Researchers conclude from the study that Belimumab displayed a stable safety profile with no new safety signals and minimal organ damage progression over eight years.

Reference : Ronald F van Vollenhoven, Sandra V Navarra, Roger A Levy, Mathew Thomas, Amy Heath, Todd Lustine, Anthony Adamkovic, James Fettiplace, Mei-Lun Wang, Beulah Ji, David Roth, Long-term safety and limited organ damage in patients with systemic lupus erythematosus treated with belimumab: a Phase III study extension, *Rheumatology*, , kez279, <https://doi.org/10.1093/rheumatology/kez279>

Possible Reason for Earlier Discontinuation of TNF- α Inhibitor Therapy in Female Patients with Inflammatory Bowel Disease

In a recent study enrolled 529 patients, found that persistence to treatment with a tumor necrosis factor (TNF) alpha inhibitor for the inflammatory bowel disease (IBD) appears to be lower among female than male patients. And the reason for the treatment discontinuation is side effects, the rate of which is being higher in women than in men. The analysis involved 529 patients (49.9% male) contributing to 631 treatment episodes (357 infliximab, 240 adalimumab and 34 with golimumab) and 2,280 TNF alpha inhibitor treatment years. Males were more likely to be treated with infliximab (69.3% vs 57.0% $p=0.003$), whereas females were more commonly prescribed adalimumab (38.4% vs 27.3% $p=0.006$) and more likely to receive a third TNF- α inhibitor (3.4% vs 0.4% $p=0.003$).

In total, 289 (45.8%) patients discontinued TNF- α inhibitor therapy. The most common reason for discontinuation was secondary loss of response, followed by side effects. Frequently reported side effects were allergic reactions (28.6%), infections (19.0%), dermatological reactions (14.3%), neurological (11.1%) and joint complaints (7.9%) TNF- α inhibitor discontinuation was significantly associated with female sex (adjusted hazard ratio [aHR], 1.42, 95% CI, 1.16–1.74), greater age at start of therapy per decade (aHR, 1.15, 1.04–1.27) and dose escalation (aHR, 3.74, 2.78–5.02).

In total cohort cause-specific analysis, female sex was associated with only side effects as a reason for discontinuation (aHR, 4.05, 2.36–6.98). On the other hand, discontinuation due to secondary loss of response was related to the use of adalimumab (aHR, 1.70, 1.11–2.60) or golimumab (aHR, 4.97, 2.30–10.74) and dose-escalation (aHR, 7.71, 5.28–11.26). There was no clear explanation for female sex is associated with reduced TNF alpha inhibitor drug persistence. However, previous reports indicate that females, in general, appear to have a greater susceptibility to dose-related adverse drug reactions possibly as a result of several differences in pharmacokinetics and pharmacodynamics between males and females (eg: differences in percentage body fat or hepatic clearance due to reduced or enhanced activity of cytochromes). Evidences also suggest that sex hormones interact with drug metabolism and mechanism of action, potentially leading to differences in efficacy and side effects. Other factors proposed to influence sex-related differences include a female predominance seen in functional pain syndrome, including bowel diseases, as well as disparities in health seeking behaviour.

Reference : Schultheiss JPD, Brand EC, Lamers E, Berg WCM, Schaik FDM, Oldenburg B et al. Earlier discontinuation of TNF- α inhibitor therapy in female patients with inflammatory bowel disease is related to a greater risk of side effects. *Alimentary Pharmacology and Therapeutics* 2019;50:386-396. <https://doi.org/10.1111/apt.15380>

DEPARTMENT ACTIVITIES

Basic Life Support and Advanced Cardiovascular Life Support Courses

Basic Life Support (BLS) course offered by American Heart Association was provided to V year Pharm.D students on 24th July 2019 at Sri Rajendra Auditorium, JSS College of Pharmacy, Mysuru. The BLS guidelines were provided to the students one month prior to the course. During the course, the students got training in essential skills individually, as part of a team, and as team leader in different learning stations based on simulated clinical scenarios. The students learned the basics of resuscitation like chest compressions, adult and infant breaths, management of choking in adults and infants etc. Realistic simulations were focused on the following key concepts: proficiency in recognizing and initiating early management of peri-arrest conditions, of choking and the supportive care, identifying and treating, recognizing other life-threatening clinical situations such as cardiac arrest and providing initial care, applying BLS algorithms and effective resuscitation team dynamics. A total of 35 fifth year Pharm.D students successfully completed the training course and received the American Heart Association Basic Life Support certification card.



Fifth Pharm.D students during BLS training

Advanced Cardiovascular Life Support (ACLS) course offered by American Heart Association was provided to VI Pharm.D students (Interns) on 25th & 26th July 2019 at Sri Rajendra Auditorium, JSS College of Pharmacy, Mysuru. The ACLS guidelines were provided to the students one month prior to the course. During the course, the students got training in essential skills individually, as part of a team, and as team leader in different learning stations based on simulated clinical scenarios. Realistic simulations were focused on the following key concepts: proficiency in basic life support care, recognizing and initiating early management of peri-arrest conditions, managing cardiac arrest, identifying and treating ischemic chest pain and acute coronary syndromes, recognizing other life-threatening clinical situations such as stroke and providing initial care, ACLS algorithms and effective resuscitation team dynamics. Only those students who passed the written test were required to participate in a Mega code testing station which evaluated the achievement of the course objectives by the students. A total of 39 Pharm.D interns successfully completed the course and received the American Heart Association Advanced Cardiac Life Support certification card.



Pharm.D interns during ACLS training

International Clinical Rotations of Pharm.D Interns of JSS AHER, Mysuru

As part of the Memorandum of Understanding (MoU) between **Southern Illinois University, Edwardsville (SIUE), United States of America (USA)** and JSS Academy of Higher Education and Research (JSS AHER), Mysuru, **Ms. Joann Joji**, Pharm.D Intern of JSS College of Pharmacy (JSSCP) Mysuru and **Ms. Veena Viswanathan** from JSSCP, Ooty campus underwent clinical rotation at SIUE. This clinical rotation helped them to gain a shadowing experience under the guidance of a preceptor, Dr. Kelly Gable at Family Care Health Centre in Carondelet and Manchester for a period of eight weeks, from 29th April to 21st June 2019.



Ms. Veena and Ms. Joann at SIUE, USA

They routinely attended the patient interviews, discussed about the cases with the preceptor and worked on certain drug queries related to the use of various antipsychotics and their pharmacokinetics. The clinical rotation gave a brief understanding of mental health that they had never come across during their clinical rotations in India, which served as a new learning experience. Besides, they also got an opportunity to attend the poster presentation of Pharm.D students of SIUE on 6th May 2019 and a Naplex review with them on 9th May 2019. They met Ms. Olivia and Alyse, the SIUE students who had earlier visited the JSS AHER campuses as a part of their student study exchange program and also James, Catherine, Caleb and Lauren, who are going to visit JSS AHER in the month of October 2019 for their Advanced Pharmacy Practice Experience rotation. Interns were fortunate to complete the 8 hour course of Mental Health First Aid (MHFA) in Missouri and got certified as trainers to provide initial help to people experiencing mental health disorders such as depression, anxiety, psychosis, and substance use disorders.



Ms. Joann and Ms. Venna with Dr. Gable, during MHFA training

Also students got a chance to shadow the staff at Medicine Shoppe where they got an insight about the workflow of a retail pharmacy in USA. Interns also shared their experience

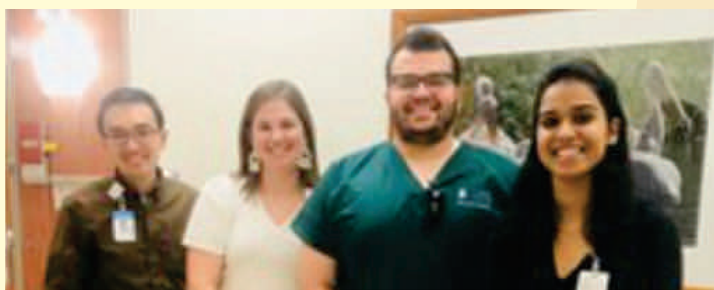
with the high school students from the SIUE Healthcare Diversity Camp who spent their day at the campus and also gave an insight to Psychiatry Pharmacy along with Dr. Gable. During their rotations, SIUE students hosted a cultural diversity lunch and they had celebration nights called the 'Indian Food night' and the 'American Food night' to share our cultures and cuisine with one another.

As part of the MoU between **University of North Carolina (UNC) at Chapel Hill, USA** and JSS AHER, Mysuru, **Ms. Grishma Grace John**, Intern of JSSCP, Mysuru pursued two months international clinical rotation at UNC from 1st May to 28th June 2019. During the rotation, she got a chance to work at various specialities such as Pulmonary Medicine, Pharmacy administration, Cardiology, Oncology (General, Pediatric and Infusion Pharmacy), Pediatrics, Obstetrics and Gynecology, Emergency Medicine, Infectious Diseases Clinic, Head and Neck Cancer clinic, Breast Cancer clinic and various transplant units under different preceptors.



Ms. Greeshma at UNC, USA

During her rotation, she actively participated in the case discussion with the respective preceptors, presented seminars assigned to her and attended various webinars where the UNC residents presented case reports. In some of the rotations, she was involved in medication reconciliation and patient counseling specially for the transplant patients.



Ms. Greeshma with her Peceptors at UNC Hospital

Also, she visited North Carolina State University and the National Museum. She attended the international food festival at Raleigh during a weekend with her student ambassador; Ms. Toneth Sang and met a couple of other pharmacy students at the festival. Also, she interacted with Mr. Akash Patel, the UNC student who had visited JSS AHER earlier under the Student Study Exchange Program. She travelled to New York by the end of her posting where she met her JSS AHER alumni working over there. Overall, Ms. Greeshma expressed that she had a truly amazing experience to be at UNC Hospitals.

International Clinical Rotation of Interns of Howard University, USA

As a part of MOU between JSS AHER, Mysuru and Howard University, USA, two students Ms. Alisha M. Bailey and Ms. Ngozika Odigbo arrived on 29th July 2019 at JSS College of Pharmacy, Mysuru under student study exchange program. The objective of the experiential program is 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



Howard University students with Dr. M Ramesh (HoD, Department of Pharmacy Practice), Dr. T M Pramod Kumar (Principal, JSSCP, Mysuru), Dr. Madhu (Deputy Director Academics, JSS AHER), Dr. B Manjunatha (Registrar, JSS AHER) and Dr. B Suresh (Pro Chancellor, JSS AHER)

period of 5 weeks duration from 30th July to 29th August 2019. During their rotation, students were introduced to various activities of Clinical Pharmacy Department. They were posted to Medicine and Paediatrics department for a period of one week each to learn about most common diseases and the

patient care services. During the posting, they could understand the difference in the management of most of the common diseases in India and in USA.

Also, they were exposed to activities of various departments like Pulmonology and DOTS centre, Immunization centre, Cardiology, Emergency, Psychiatry, Dermatology and Gastroenterology departments. They reviewed several cases from departments and discussed them with their respective facilitators. They had presented a case each on Dengue and Leptospirosis as part of their assignments required for their posting at JSS AHER. They attended the case presentations with Pharm.D Interns of JSS AHER. They were posted to Asha Kirana Hospital and Bharath Hospital and Institute of Oncology for a period of one week to learn about various opportunistic infections along with HIV and Cancer management respectively. They were posted at JSS College of Pharmacy, Ooty in the last week to give them an experience on practice of health care system in Government Hospital.



Howard University students with department staff

Interaction Session by Pharm.D Students from USA

Pharmacy Education Unit (PEU) and Department of Pharmacy Practice, JSS College of Pharmacy, Mysuru organized an interaction session on 'Pharm.D Education and Career Opportunities in USA' for First and Second year Pharm.D students of JSS College of Pharmacy, Mysuru at Seminar Hall, Department of Pharmacy Practice on 16th August 2019. Ms. Shloka Sahetya, Pharm.D Student at Albany College of Pharmacy and Health Sciences, New York, USA, and Ms. Alisha Bailey and Ms. Ngozika Odigbo, Pharm.D Interns at Howard University College of Pharmacy, Washington, USA interacted with the Pharm.D students. Ms. Alisha Bailey and Ms. Ngozika Odigbo were



Ms. Shloka, Albany College of Pharmacy and Health Science, USA during the session

undergoing their international clinical rotation at Department of Clinical Pharmacy at JSS Hospital, Mysuru. The aim of this interaction session was to create an awareness among Pharm.D students of JSS College of Pharmacy, Mysuru about the Pharm.D education and career opportunities in USA

Ms. Shloka Sahetya explained her experience at Albany College of Pharmacy and Health Sciences starting from the admission process, subjects in first two years of pre-professional course, examination pattern and results structure. She responded to the various questions asked by the students and facilitators about the Pharm.D education in USA. Ms. Alisha Bailey and Ms. Ngozika Odigbo gave a presentation on 'Introductory Pharmacy Practice Education (IPPE), Advanced Pharmacy Practice Education (APPE) and Career Opportunities in USA for Pharm.D Students. During this presentation, they explained about the structure of Pharm.D education in Universities at USA and pattern of Experiential Program Courses and Experiential Education in USA. Also, they have briefed about on NAPLEX (Licensure Examination in USA) and different career opportunities in USA. Participants had fruitful interaction and cleared all their doubts about Pharm.D education in USA.

Seminar on 'Protocol Writing'

Pharmacy Education Unit (PEU) of JSS College of Pharmacy, Mysuru in association with Department of Pharmacy Practice conducted a Seminar on 'Protocol Writing' on 4th July 2019 at Seminar Hall, JSS College of Pharmacy, Mysuru. The aim of this seminar was to enhance the understanding on and impart skills of Protocol Writing among the research scholars, second year M. Pharm and fifth year Pharm.D students who are about to start their research projects involving human subjects. Mrs. Shilpa Palaksha, Assistant Professor, Department of Pharmacy Practice delivered a talk on '*Components of a Protocol for Human Observational Studies*'. During this talk, Mrs. Shilpa highlighted the importance and various components of a protocol. The second topic of the seminar was '*Comprehensive Literature Search*' that was delivered by Dr. Sri Harsha Chalasani, Lecturer, Department of Pharmacy Practice. In this session, Dr. Sri Harsha explained about the search strategy for locating published literatures from different databases. Following this, Mrs. R. S. Savitha, Assistant Professor, Department of Pharmacy Practice delivered a talk on '*Study Designs and Research Methodology*'. During this talk, Mrs. Savitha highlighted the importance of methodology part in a protocol and various aspects of a research methodology.

Mr. Krishna Undela, Lecturer, Department of Pharmacy Practice delivered a talk on '*Statistical Analysis*'. Mr. Krishna



During seminar on protocol writing

explained the calculation of descriptive and inferential statistics with examples. The last topic of the seminar was '*ICMR Ethical Guidelines for Human Studies*' that was delivered by Mr. S. Balaji, Lecturer, Department of Pharmacy Practice. During this talk, Mr. Balaji briefed about importance of ethics in research and highlighted the various aspects of ICMR Ethical Guidelines. About 60 students from Departments of Pharmacy Practice and Pharmacology participated in the seminar. Students expressed that this seminar helped them in understanding the key components of a Protocol and how to write an effective protocol for human observational studies.

Participation in International Day Against Drug Abuse & Illicit Trafficking

Department of Pharmacy Practice, JSS College of Pharmacy, JSS AHER, Mysuru actively participated in the rally on the occasion of 'International Day Against Drug Abuse & Illicit Trafficking' jointly organised by Drugs Control Department, Mysuru Division and Railway Protection Force held on 26th June 2019 in Mysuru. The aim of the rally was to create awareness among publics on ill effects of drug abuse and different methods that need to be adopted by common people to overcome drug abuse & illicit trafficking. The rally was carried out within the premises of railway station.



Inauguration of rally on the occasion of International Day against Drug Abuse & Illicit Trafficking



Pharm.D students during the rally

Mr. Nagaraj, In-charge Drug Controller, Mysuru Division inaugurated the rally. Mr. Harish, Mr. Kallid, Mr. Ramesh and Ms. Asha Latha, Drug Inspectors from Mysuru division were present during the rally. Around 30 Pharm.D and M. Pharm Pharmacy Practice students along with staff actively participated in the rally.

Guest Lectures Organized by the Department

The Special Interest Group (SIG) – Quality and Safe Use of Medicine in association with Department of Pharmacy Practice organised a guest lecture on '*Medical Products Safety Surveillance System: India and WHO Perspective*' on 18th May 2019 at Seminar Hall, Department of Pharmacy Practice, JSS College of Pharmacy, Mysuru. **Dr. V. Kalaiselvan**, Principal Scientific Officer, Indian Pharmacopoeia Commission, Ministry of Health & Family Welfare, Government of India delivered a lecture.



Dr. Kalaiselvan delivering the lecture

He began lecture with the salient features of Indian Pharmacopoeia 2018, wherein he mentioned that there are 2935 indigenously developed monographs in the Indian Pharmacopoeia. These monographs include drugs, drug excipients, blood & its products, Herbals, radio pharmaceuticals etc. Also, he briefly addressed the gathering on establishment of Pharmacovigilance Programme of India (PvPI), Materiovigilance Programme of India (MvPI) by Ministry of Health & Family Welfare and also the collaboration of National Coordinating Centre – PvPI with World Health Organisation (WHO) for Pharmacovigilance in Public Health Programme. Pharm.D and M. Pharm Pharmacy Practice Students and PhD Research Scholars attended the session and interacted with the speaker. At the end of the session, Dr. Sri Harsha Chalasani, Lecturer, Dept. of Pharmacy Practice, JSS College of Pharmacy, Mysuru thanked the speaker for his excellent and informative talk that benefitted the audience.

The Special Interest Group (SIG) - Quality and Safe Use of Medicine, Pharmacy Education Unit in association with Department of Pharmacy Practice, JSS College of Pharmacy, Mysuru organized a Guest Lecture on '*Medication Therapy Management*' on 2nd August 2019 at Seminar Hall, Department of Pharmacy Practice, JSS College of Pharmacy, Mysuru. **Dr. John Jacob**, MTM Pharmacist, Operations and Planning, Walgreens Boots Alliance and Affiliate Assistant Professor, University of Florida, Nova Southeastern University was the speaker. The objective of this lecture was to make the students understand about the roles and responsibilities of pharmacist in Medication Therapy Management (MTM) and the importance of medication safety. During his lecture, Dr. Jacob also discussed in detail about the core components, process and outcome, scope and rationale of MTM. Also, he explained about the scope of MTM in ambulatory patients. Dr. Jacob shared his personal experience as an MTM pharmacist. At the end of his presentation, he briefed about the pharmacy careers in USA,

how to register as a pharmacist in US, and also about exams to be taken for licensure and registration. At the end of the session, participants got an opportunity to interact with the speaker and clarify their doubts.



Mr. Jacob delivering lecture

Dr. Salahuddin Khan Ghori, Deputy Medical Superintendent, JSS Hospital, Mysuru delivered guest lecture titled "*Pearls and Pitfalls in Patient Safety: Role of Clinical Pharmacists in Hospitals*" on the behest of the Department of Pharmacy Practice, JSS College of Pharmacy – Mysuru & **Special Interest Group – Quality & Safe Use of Medicine** for the benefit of Pharm.D (Interns) and Post Graduate students of Pharmacy Practice which was held at Seminar Hall, Department of Pharmacy Practice, JSS College of Pharmacy, Mysuru on 27th August, 2019. The role of clinical pharmacist alongside with doctors in hospital was emphasised throughout the session and latest advancements in the patient safety frame-work, such as computerised physician order entry system (CPOE), promotion of unit dose dispensing systems to facilitate the rational use of medicines, assisting the doctors and nurses in optimising the therapeutic benefits were discussed in detail. Students received the lecture with great anticipation and clarified their doubts regarding the career opportunities in the Hospital settings.



Dr. Ghori during his lecture

DRUG ALERTS

National Co-ordinating Centre (NCC), Pharmacovigilance Program of India (PvPI), released the following drug alerts and requesting healthcare professionals to report (18001803024) to ensure patient safety.

1. Cetrizine may cause Tachycardia.
2. Dabigatran may cause Alopecia.
3. Sertraline may cause Maculopathy.
4. Amiodarone may cause Acute Pancreatitis.

Faculty Delivered Guest Lectures

Dr. M. Ramesh, Professor & Head, Department of Pharmacy Practice delivered a guest lecture on 'Pharmaceutical, care services' during 3rd National Level Seminar on Clinical Pharma Practice – Indian and Global Scenario (CPP-IGS 2019) organised by Swamy Vivekananda College of Pharmacy, Tiruchengode, Tamil Nadu on 29th June 2019.



Dr. M Ramesh during the CPP-IGS 2019

Dr. Krishna Undela, Lecturer, Department of Pharmacy Practice, JSS College of Pharmacy, Mysuru attended the 'AICTE Sponsored Two Weeks Faculty Development Program held at Raghavendra Institute of Pharmaceutical Education & Research (RIPER), Anantapuramu on 21st June 2019 as a Resource Person, and conducted a workshop on 'Meta-analysis and Systematic Reviews'.



Dr. Undela during the workshop

Inter Professional Educations

Inter Professional Education (IPE) on Hypertension was held on 14th August 2019 at Lecture Hall-1 at JSS Hospital, Mysuru. Eighth term students of MBBS and Pharm.D interns attended the session. Eighth term students presented on various aspects of Hypertension like the definition, epidemiology, types, risk factors, etiopathogenesis, complications and treatment.



During IPE on Hypertension

Ms. Jehath Syed, Pharm.D Intern discussed about the management of Hypertension alone and along with compelling indications like chronic kidney disease, ischemic heart disease, heart failure and diabetes as per the Joint National Committee 8 (JNC 8) and American College of Cardiology / American Heart Association (ACC / AHA) guidelines. Dr. Chandana S, Senior Resident, Department of General Medicine, JSS Hospital and Dr. Krishna Undela Lecturer, Department of Pharmacy Practice, JSS College of Pharmacy, Mysuru facilitated the IPE session.

Inter Professional Education on Thyroid Disorders was held on 28th August 2019 at JSS Hospital Mysuru. The session was attended by 9th term Medical Students, Pharm.D interns, and PG students of Pharmacy Practice. Medical students presented the various aspects of thyroid disorders including the epidemiology, etiology, and pathophysiology of hypo- and hyper-thyroidism. Management of these disorders was also discussed including doses of drugs used, dose titration during therapy, and monitoring therapy. Pharmacy Practice students discussed on the adverse effects associated with thyroid drugs and their management. Presentations were facilitated by Dr. Sneha S R, Senior Resident, Department of Medicine, Dr. Divakar S R, Assistant Professor, Department of Surgery, Dr. Hemapriya L, Associate Professor, Department of Obstetrics and Gynecology, Dr Chandrashekar Professor, Department of Paediatrics and Dr. UR Rakshith, Lecturer Department of Pharmacy Practice. The facilitators are staff of JSS Medical College, JSS Hospital and JSS College of Pharmacy Mysuru.



During IPE on Thyroid Disorders

Visit of Faculty from La Trobe University, Australia

Dr. Sabrina Gupta, Associate Lecturer, Dept. of Public Health, **Dr. Jency Thomas**, Lecturer, Dept. of Physiology, Anatomy and Microbiology and **Dr. Markandeya Jois**, Senior Lecturer, Dept. of Physiology, Anatomy and Microbiology, La Trobe University, Australia visited Department of Clinical Pharmacy located at JSS Hospital, Mysuru from 17th to 19th July 2019. The purpose of the visit was to train the La Trobe – JSS AHER PhD research scholar Puvvada Rahul Krishna on conducting face to face interviews with the general physicians and pharmacists for his Ph.D work.



Staff of JSS AHER and La Trobe University with La Trobe – JSS AHER PhD Research Scholars

During the visit, they were briefed about the activities of Dept. of Clinical Pharmacy such as reporting of ADRs, AEFI and Medication Incidents and patient medication



Faculties of Latrobe University with Dr. M Ramesh and the research scholar

counselling process with a special emphasis on ambulatory patient care and JSS medication information for neuropsychiatric disorders & sensitization (JSS MINDS) Initiatives. Later the Staff and Research Scholars of Dept. of Pharmacy Practice interacted with the Staff of La Trobe University.

Faculty attended International Conference

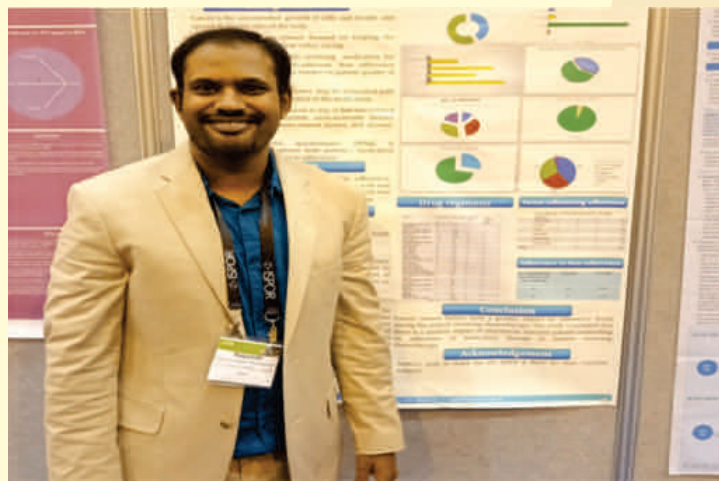
Dr. T M Pramod Kumar, Principal, JSSCP and **Dr. U R Rakshith** Lecturer, Dept of Pharmacy Practice attended the International Society of Pharmacoeconomics and Outcome Research (ISPOR) Annual conference themed with Rapid, Disruptive, Innovative: A New Era in Health Economics and Outcome Research was held during 18th to 22nd May 2019 at Ernest Morial Conventional Center New Orleans, Louisiana USA. Dr. Rakshith presented a poster entitled “Assessment of medication adherence and non-adherence among cancer patients receiving chemotherapy” during the conference. Dr. Pramod Kumar presented three papers entitled

'Haemovigilance: Adverse Reactions Following Blood Transfusions - A Cross Sectional Study In A Developing Country', 'Can Ayushmann Bharat Alter India's Healthcare Landscape?' and 'Jan Aushadi scheme: an initiative in making quality generic medicines at affordable prices'.

During the conference, they had an opportunity to meet professionals and create new contacts with the personal working on Health economics and outcome research. The conference also gave a platform to show the research carried out at the Department of Pharmacy Practice at global level and share the experience with other researcher in the same research field.



Dr. T M Pramod Kumar and Dr. Rakshith during ISPOR conference



Dr. Rakshith during post presentation

Awards / Recognitions

Mr. George Mathew Panachiyil and Ms. Tirin Babu, Pharm.D interns received a **Certificate of Appreciation** from JSS AHER, Mysuru for being selected as reviewers for prestigious academic journals, 'Journal of Pharmacy Practice' and 'Dermatologic Therapy' on 30th May 2019.



Mr. George and Ms. Tirin with Dr. R S Bhat, Controller of Examinations and Dr. B. Manjunatha, Registrar, JSS AHER, Mysuru

Ms. M Laasya, Pharm.D intern won **3rd Place in Pharmacist Intervention Contest** conducted on 16th August 2019 by Clinicon organized by Center for Pharmaceutical Sciences, Institute of Science and Technology, JNTU, Kukatpally, Hyderabad in collaboration with Pharmacon Society for Pharmacy Practice and Clinisol Research Private Limited



Ms. Laasya Receiving the prize

Mrs. Shilpa Palaksha, Assistant Professor of Department of Pharmacy Practice identified as **Subject Expert to Baba Atomic Research Centre (BARC)** for Pharmacist Interview.

Dr. Oliver Joel Gona, Research Scholar of Department of Pharmacy Practice received a **Fellowship** of INR 10000/- per month from JSS AHER, Mysuru for a period of one year from June 2019.

Dr. P Rahul Krishna, Research Scholar of Department of Pharmacy Practice pursuing Ph.D under JSS AHER, Mysuru and La Trobe University, Australia collaborative PhD Program received scholarship of INR 25,000/- per month from April 2019.

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.

We extended our services 24x7 from 8th October 2018 for the benefit of HCPs and Patients.

24x7 Mobile Number: 6363539153, Toll free Number - 1800-425-0207

Land line Number: 2335555, Extn - 5577

E-mail: dic.jsscp@jssuni.edu.in; pic.jsscp@jssuni.edu.in

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

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