PHARMACY PRACTICE

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DEPARTMENT OF PHARMACY PRACTICE
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NEWS LETTER

ABOUT SLEEP-DISORDERED BREATHING AND OBSTRUCTIVE SLEEP APNEA

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WHAT IS SLEEP-DISORDERED BREATHING?

Sleep-disordered breathing includes conditions that cause difficulty breathing while you sleep.There are various types but the most common among these is obstructive sleep apnea.

Obstructive sleep apnea can cause you to stop breathing repeatedly during sleep.This may occur only a few times per night, or in severe cases,hundreds of times per night.As you fall asleep your muscles relax,including the muscles of the upper airway.This can cause an obstruction in the airway if there is collapse of tissue in the back of the throat.This collapse can lead to a pause in breathing,also called apnea,which is usually temporary.The airway becomes blocked which limits the amount of air reaching your lungs and can reduce your oxygen levels.Your organs,especially the brain,are highly dependent on oxygen.When this blockage happens you may also snore or make choking noises while breathing.

WHAT ARE THE SIGNS OF OBSTRUCTIVE SLEEP APNEA?

Some common signs of sleep apnea include the following:

1 .Loud or frequent snoring
2. Pauses in breathing while sleeping
3. Choking noises while sleeping
4. Waking up after sleep but not feeling refreshed
5. Increased daytime sleepiness
6. Falling asleep easily during monotonous activity
7. Difficulty concentrating
8. Morning headaches
9. Memory loss

WHAT ARE THE RISK FACTORS FOR OBSTRUCTIVE SLEEP APNEA?

The main risk factor for sleep apnea is being overweight or obese. Other risk factors include having a large neck size, male sex, middle age,high blood pressure, smoking, and a family history of sleep apnea.

HOW IS SLEEP APNEA DIAGNOSED?

A sleep medicine doctor can diagnose sleep apnea by taking a careful history to look for common symptom and then performing a sleep study. The sleep study can be done at home or in sleep laboratory.

WHAT ARE THE TREATMENTS FOR SLEEP APNEA?

1. Weight loss is a conservative treatment for sleep apnea. It is thought to work by reducing extra neck tissue, which may be causing collapse of the airway.
2. Behavioral changes can help improve apnea symptoms.These include quitting smoking and not drinking alcohol.Alcohol relaxes throat muscles, which can

cause airway collapse.
3. Positional therapy is a behavioral strategy that encourages people to sleep on their side rather than on their back. It involves wearing a brace to help maintain a side sleeping position.It alerts the sleeper(via vibration) if he or she moves to a back sleeping position.
4. Continous positive airway pressure (CPAP) involves using a machine that provides continuous flow of air to maintain an open airway. This is most beneficial when used regularly during sleep.
5. Oral appliance therapy is used in patients who cannot tolerate CPAP. It involves using an oral device that resembles a mouth guard. The device holds the tongue or jaw in position to prevent the airway from collapsing. A dentist can help fit you for an oral appliance.
6. Upper airway surgery is sometimes considered when CPAP and oral appliances are ineffective. This can also be considered if there is a definite surgically correctable problem that is obstructing the airway such as very large tonsils or adenoids.

DEPARTMENT ACTIVITIES

PARTICIPATION IN MEDICAL CAMPS

St. James Hospital and Dept. Of pharmacy practice jointly organized a medical camp at Kannampuzha temple ground, Chalakudy during the temple festival on 02-03-2017 from 10.00 am to 10.00p.m.The activities rendered by our Pharm D students include:

- Blood Sugar Monitoring
- B.P Monitoring
- B.M.I checking

Pharm D interns (2011 batch) participated in the medical camp organized by St.James Hospital and CLC, Chaipumkuzhi on 19-03-2017 from 9.00 am to 2.30 p.m at Chaipumkuzhi. Services provided by the students include:

- Patient counseling
- Assistance in dispensing of medicines
- Pulmonary function test
- Blood Sugar Monitoring
- B.P Monitoring
- B.M.I checking

Assistance in dispensing of medicines

Patient counseling during the camp

A medical camp - "Happy Chalakudy, Aarogyamela" was organized by IMA, Rotary Club, AIMS, Kochi, Govt.Hospital and St.James Hospital, Chalakudy on 04-06-2017 from 8.00 am to 2.30 p.m at Carmel School, Chalakudy for public health safety by providing free medical checkup. PharmD interns provided patient counseling and assisted in drug dispensing.

Medical camp (Happy Chalakudy –Arogyamela) at Carmel School

Medical camp (Happy Chalakudy –Arogyamela) at Carmel School

Participation in Students Forum- Pharmacy Practice, Current Practice and Future Perception

(for the students and by the students)

Students forum is to evaluate the current practicing pharmacy through students perspective and implementing the wants to the future practices. A one day programme entitled "Students Forum- Pharmacy Practice, Current Practice and Future Perception" was organized by Dept. Of pharmacy practice, PSG College of pharmacy, Coimbatore on 21-04-2017. Our two Pharm D interns Ms. Merin Anto and Ms. Aneesha P.K delivered talks on "community awareness programmes" during the session.

Presentation by Ms.Aneesha P.K,Pharm D Intern (2011 batch) at PSG College of Pharmacy

(2011 batch) at PSG College of Pharmacy

V PHARM D ORIENTATION PROGRAMME

Orientation programme for 2013 batch Pharm D was conducted at Govt.Taluk Head Quarters hospital, Chalakudy on 22-08-2017.Rev . Fr.Lijo Kongoth,Associate Director,St James group of institutions, Dr. K. Krishnakumar, Principal, St.James College of Pharmaceutical Sciences, Dr.M.G Sivadas,Medical Superintendent , Mrs.M.C Mary, Nursing Superintendent,Govt.Taluk Head Quarters Hospital, Chalakudy , V Pharm D students and faculty members of St. James College of Pharmaceutical Sciences Participated in the Programme.

PHARM D INTERNSHIP ORIENTATION PROGRAMME

Pharm D (2012 Batch) internship orientation programme was held at St. James Hospital on 31-07-2017 to 02-08-2017.The three day programme was inaugurated by Rev. Fr. Varghese Pathadan.Director, St.James group of institutions.The sessions included were

DAY 1

"Medication errors & role of clinical pharmacist to avoid medication errors "and "Implementing clinical pharmacy services in Private Hospitals" by Dr.A.Vijayakumar, Chief clinical pharmacist & Pharmacy manager, KMCH Hospital, Coimbatore.

"Body language & barriers of communication" by Dr. L. Panayappan, H.O.D, Pharmacy Practice, St.James College of Pharmaceutical Sciences.

DAY 2

"Team management" by Rev.Fr. Varghese Pathadan. Director, St.James group of institutions.

"Hospital Statutory procedures" by Mr. James Manjooan , HR Manager,St.James Hospital.

"Hospital overview" by Sr. Rachel C.S.C, Nursing Superintendent, St.James Hospital

"Role of Pharm D intern in Hospital"by Dr. Manoj T.K., Neuro Surgeon, St James Hospital

"Hospital Infection control practices" by Mrs. Sibi Devassikutty,Nurse Manager ,St James Hospital.

DAY 3

"Duties & responsibilities of Pharm D interns in Hospital" by Dr.Arathy Joy, Clinical Pharmacist,St James Hospital.

"Drug Dosage calculations "by Mrs. Betcy Jose,Quality Control Department, St James Hospital.

"Dilution Techniques of medications" by Dr. Niroop P.K., General Physician, St James Hospital.

"Patient health education" by Dr. Mrs. Mercy Bosco, Principal, St.James college of nursing.

Pharm D Internship Orientation Programme at St.James Hospital

WORLD PHARMACIST DAY CELEBRATION

The world pharmacist day celebration at St.James College of Pharmaceutical Sciences was inaugurated by Rev .Fr.Lijo Kongoth, Associate Director, St James group of institutions on 25th September 2017.The Chief Guest of the programme was Mr.David Palayoor,Technical Director,Variety fling Pharma,Thrissur.He also delivered a talk on the opportunities of pharmacy graduates and post graduates.

Inauguration Pharmacist day celebration

ONE DAY SEMINAR

Department of Pharmacy Practice organized a one day seminar on 21-08-2017 at St.James College of Pharmaceutical Sciences. The pogramme was inaugurated by Rev.Fr. Varghese Pathadan, Director, St. James group of institutions. The sessions were "The art of scientific presentations" by Dr.A Shyam Sundar, Associate Professor, University of Nizwa, Oman and "Medication adherence for better therapy outcome" by Dr.B.Rajalingam, Associate Professor, SRIPMS, Coimbatore.The seminar also included a training programme for the faculty members by Dr.A Shyam Sundar on the topic "Outcome based education".

Inauguration of Seminar

PHARMACY PRACTICE MODULE

Dr. K. Krishnakumar, Principal,St. James College of Pharmaceutical Sciences was one of the organizing members of Pharmacy Practice Module conducted at Devakiamma college of Pharmacy,Malappuram in association with IACP, Channai on 23rd to 25th September 2017.

Honouring Dr. K. Krishnakumar, Principal, St. James College of Pharmaceutical Sciences during Pharmacy practice Module

Dr. K. Krishnakumar, Principal, St. James College of Pharmaceutical Sciences was the chief guest in the inauguration of Pharm D course in KTN College of Pharmacy, Chalawara,Ottapalam on 18th August 2017 .

Dr. K. Krishnakumar,Principal, St.James College of Pharmaceutical Sciences gave felicitation during the Annual Sports Day conducted at SRIPMS,Coimbatore on 30th June 2017.

Dr. K. Krishnakumar,Principal, St.James College of Pharmaceutical Sciences delivering Lecture on " Stero-chemistry and drug Action" at Vidhyanikethan college of Pharmacy, Tirupati, Andhra Pradesh on 4th september 2017

PUBLICATIONS

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ADR REPORTED TO OR DETECTED BY DEPARTMENT OF PHARMACY PRACTICE

DRUGS	CATEGORY	ROUTE	ATURE OF ADR
Gentamycin	Antibiotic	iv	Redness and itching in both palms
Telmisartan +Chlorthalidone	Antihypertensive	Oral	Hyponatremia and hypokalemia
Imipenem +Cilastacin	Antibiotic	iv	Rashes
Ciprofloxacin	Antibiotic	iv	Itching on tongue
Ceftriaxone	Antibiotic	iv	Edema and redness
Heparin	Anticoagulant	Topical	Redness and itching
Pioglitazone	Antidiabetic	Oral	Pedal edema
Paracetamol	Nsaids	Oral	Itching all over the body
Ferrous Fumarate +Folic Acid	Haematinic	Oral	Itching
Atorvastatin	Antihyperlipidaemic	Oral	Myalgia
Spiranolactone	Diuretic	Oral	Gynacomastia
Garamycin	Antibiotic	iv	Giddiness and tinnitus
Salbutamol	Bronchodilator	Inhalation	Tremor

SEMINARS AND CONFERENCES

1. Mrs. Meppil Baby, Mrs.Rosmin Jacob, Dr Alfet Raju and Mrs. Tiny Rose attended National Seminar cum Workshop on the topic "Multiple Facets of Pharmacovigilence at Chemist College of Pharmaceutical Sciences on 14th October 2017

2.Mrs.Lincy George, Mr.Leo Mathew , Mrs.Rosmin Jacob attended One day workshop for PG Thesis Guides from Affiliated Colleges conducted at Kerala University of Health Sciences, Thrissur on 11th August 2017

3.Dr.K.Krishnakumar, Dr.L.Panayappan and Dr.Jayaprakash attended The Leadership Development Conclave organized by IACP and PCI at Poovar, Trivandrum,Kerala,from 1st to 3rd May 2017

4.Dr. L. Panayappan, Dr. Grace Thomas and Students of Department of Pharmacy Practice attended Achiever's Forum – Pharmacy Practice, Current Practice and Future Perception organized by Department of Pharmacy Practice , held on 21st April 2017 . Me in Anto and Aneesha P.K invited as speakers and presented the topics related to "AWARENESS PROGRAMMES" under the session "COMMUNITY PHARMACY".

5. Dr.K.Krishnakumar, Dr.L.Panayappan ,Dr.Grace Thomas and students of department of pharmac practice attended Indian Association of Colleges of Pharmacy's 1st Pharmaceutical Sciences Congress 2017 held at Ramaiah university of Applied Sciences,Bengaluru on 18th and 19th March, 2017

6. In the National Research day2017 held at Amrita school of pharmnacy, Amrita Vishwa Vidyapeetham, Amrita University, Kochi on 17th and 18th March 2017, Mrs.Meppil Baby participated for the oral presentation entitled "A prospective study on potential drug- drug interactions in General Medicine department at a tertiary care hospital" and Mr.Leo Mathew presented a poster entitled "Acomparative study on the role of varios anti-ulcer drugs in preventing NSAID induced GI complications".

7.Mrs. Happy Thomas ,Mrs. Tiny Rose E and students of department of pharmacy practice attended MEDS' 2017- High Reliability In Medication Process held on 18th March 2017 at GKNM Hospital.

8. Dr. K. KrishnaKumar, Dr. Grace Thomas and students of Pharmacy Practice attended Pharmacy Practice Module-Advanced Learning Series - 4 on Infectious Diseases at Devaki Amma Memorial College of Pharmacy Chelembra from 23rd to 25th September 2017

9. Dr. Grace Thomas Participated in 5th Skill Development Programme for 10 days on " Basics and Regulatory Aspects of Pharmacovigilence from 4th -13th September at IPC Delhi

DRUG PROFILE - ENASIDENIB

Date of Approval :1/8/2017
Brand: IDHIFA
Indication: IDHIFA is an isocitrate dehydrogenase-2 inhibitor indicated for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML).
Dosage and administration :The recommended starting dose of IDHIFA is 100 mg taken orally once daily with or without food until disease progression or unacceptable toxicity. For patients without disease progression or unacceptable toxicity, treat for a minimum of 6 months to allow time for clinical response.
Do not split or crush IDHIFA tablets. Administer IDHIFA tablets orally about the same time each day. If a dose of IDHIFA is vomited, missed, or not taken at the usual time, administer the dose as soon as possible on the same day, and return to the normal schedule the following day.

Dosage forms and strengths :
•50-mg tablet: Pale yellow to yellow oval-shaped film-coated tablet debossed "ENA" on one side and "50" on the other side.
•100-mg tablet: Pale yellow to yellow capsule-shaped film-coated tablet debossed "ENA" on one side and "100" on the other side.

Table 1: Dosage Modifications for IDHIFA-Related Toxicities

Adverse Reaction	Recommended Action
Differentiation syndrome	•If differentiation syndrome is suspected, administer systemic corticosteroids and initiate hemodynamic monitoring •Interrupt IDHIFA if severe pulmonary symptoms requiring intubation or ventilator support, and/orrenal dysfunction persist for more than 48 hours after initiation of corticosteroids •Resume IDHIFA when signs and symptoms improve to Grade 2* or lower.
Noninfectious leukocytosis (white blood cell [WBC] count greater than 30 x 10^9/L)	•Initiate treatment with hydroxyurea, as per standard institutional practices. •Interrupt IDHIFA if leukocytosis is not improved with hydroxyurea, and then resume IDHIFA at 100 mg daily when WBC is less than 30 x 10^9/L
Elevation of bilirubin greater than 3 times the upper limit of normal (ULN) sustained ≥2 weekswithout elevated bilirubin or other hepatic disorders	•Reduce IDHIFA dose to 50 mg daily. •Resume IDHIFA at 100 mg daily if for ≥2 weeks without elevated bilirubin elevation resolves to less than 2 x ULN.
Other Grade 3* or higher toxicity considered related to treatment including tumor lysis syndrome	•Interrupt IDHIFA until toxicity resolves to Grade 2* or lower. •Resume IDHIFA at 50 mg daily; may increase to 100 mg daily if toxicities resolve to Grade 1* or lower. •If Grade 3* or higher toxicity recurs, discontinue IDHIFA

Mechanism of Action: Enasidenib is a small molecule inhibitor of the isocitrate dehydrogenase 2 (IDH2) enzyme

Pharmacokinetics:

Absorption: The absolute bioavailability after 100 mg oral dose of enasidenib is approximately 57%. After a single oral dose, the median time to CmaX(Tmax) is 4 hours.

Distribution: The mean volume of distribution (Vd) of enasidenib is 55.8 L (CV% 29). Human plasma protein binding of enasidenib is 98.5% and of its metabolite AGI-16903 is 96.6% in vitro.

Elimination:

Metabolism: Enasidenib accounted for 89% of the radioactivity in circulation and AGI-16903, the N dealkylated metabolite, represented 10% of the circulating radioactivity.

Excretion: Eighty-nine percent (89%) of enasidenib is eliminated in feces and 11% in the urine. Excretion of unchanged enasidenib accounts for 34% of the radiolabeled drug in the feces and 0.4% in the urine.

Adverse Effects: Differentiation Syndrome

Contraindications : None

Pregnancy: Based on animal embryo-fetal toxicity studies, IDHIFA can cause fetal harm when administered to a pregnant woman.

Lactation : There are no data on the presence of enasidenib or its metabolites in human milk, the effects on the breastfed infant, or the effects on milk production.

FDA APPROVED DRUGS

S.No.	Drug Name	Indication	Date of Approval
1	Sofosbuvir 400 mg film coated Tablet	In combination with other medicinal products for the treatment of Chronic Hepatitis C (CHC) in adults	16.02.2017
2	Hydralazine tablets BP 25 mg (Additional Strength)	For moderate to severe hypertension (in conjunction with a β-adrenoceptor blocking agent or diuretic) and hypertensive crisis.	23.02.2017
3	Hydralazine tablets BP 50 mg (Additional Strength)	For moderate to severe hypertension (in conjunction with a β-adrenoceptor blocking agent or diuretic) and hypertensive crisis.	23.02.2017
4	Bendamustine hydrochloride injection 90 mg/mL (Fill volume 0.5 mL in 2 ml capacity vial & 2 mL filled in 2 mL capacity vial)	1. For the treatment of patients with chronic lymphocyticleukemia 2. For the use in Indolent B-cell Non-Hodgkin's Lymphoma (NHL) that has Progressed During or Within six months of treatment with Rituximab or a Rituximab containingRegimen.	02.03.2017
5	Eltrombopagolamine 25 mg/50 mg tablets (Additional indication)	For the treatment of thrombocytopenia in paediatric patients 1 year and older with chronic immune(idiopathic) thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins or splenectomy. (It should be used only in patients with ITP whose degree of Thrombocytopenia and clinical condition increase the risk for bleeding. It should not be used in an attempt to normalize plateletcounts).	02.03.2017
6	Azacitidine for injection 100 mg	For the treatment of adult patients with all sub-types of Myelodysplastic Syndrome **With the condition: to be sold by retail on the prescription of Oncologist only**	07.03.2017
7	Methylcobalamin 1500 mcg orally disintegrating strips	For the treatment of Diabetic Neuropathy and peripheral Neuropathy	10.03.2017
8	Cefditoren Pivoxil dry powder for suspension 100 mg/5 mL	For the treatment of mild to moderate infections in adults and adolescents (12 years of age or older) which are caused by susceptible strains of the designated microorganisms in the condition listed below • Acute Bacterial Exacerbation of ChronicBronchitis • Community-Acquiredpneumonia • Pharyngitis/Tonsillitis	30.03.2017

		• Acutesinusitis • Uncomplicated skin and skin-structure infections.	
9	Thiotepa Powder for concentrate for solution for infusion 100 mg(Additional strength & indication)	1. With or without total body irradiation(TBI), as conditioning treatment prior to allogenic or autologous hematopoietic progenitor cell transplantation (HPCT) in haematological diseases in adult and pediatricspatients; 2. When high dose chemotherapy with HPCT support is appropriate for the treatment of solid tumors in adult and pediatricspatients. **With the condition: to be sold by retail on the prescription of Hematologist only**	06.04.2017
10	Thiotepa Powder for concentrate for solution for infusion 15mg (Additional indication)	1. With or without total body irradiation(TBI), as conditioning treatment prior to allogenic or autologous hematopoietic progenitor cell transplantation(HPCT) in haematological disease in adult and pediatricspatients; 2. When high dose chemotherapy with HPCT support is appropriate for the treatment of solid tumors in adult and pediatricspatients. **With the condition: to be sold by retail on the prescription of Hematologist only**	06.04.2017
11	Bortezomib for Injection (i.v) 1 mg/vial (Additional indication)	For the treatment of patients with mantle cell lymphoma **With the condition: to be sold by retail on the prescription of Oncologist only**	11.04.2017
12	Bortezomib 3.5 mg/vial Powder for solution for injection (i.v/s.c) (Additional indication)	For the treatment of patients with mantle cell lymphoma **With the condition: to be sold by retail on the prescription of Oncologist only**	11.04.2017
13	Mesalamine Delayed Release Tablets 800 mg (Additional dosage form)	For the treatment of mild to moderate acute exacerbations of ulcerative colitis and for the maintenance of remission of ulcerative colitis. **With the condition: to be sold by retail on the prescription of Specialist/Gastroenterologist only**	11.04.2017
14	Teneligliptin Film coated Tablet 20 mg	For the treatment of Type 2 Diabetes Mellitus as a monotherapy adjunct to diet and exercise.	28.04.2017
15	Ticagrelor 60 mg tablets (Additional strength & indication)	Indicated for the prevention of thrombotic events (cardiovascular death, myocardial infarction and stroke) in patients with a history of myocardial infarction (MI occurred at least one year ago) and a high risk of developing a thrombotic event. **With the condition: to be sold by retail on the**	02.05.2017

		prescription of Cardiologist/Internal Medicine Specialityonly	
16	Daclatasvir Tablet 30 mg	"For use with Sofosbuvir for the treatment of patients with chronic hepatitis C virus (HCV) genotype 3 infection". With the condition: to be sold by retail on the prescription of Hepatologist only	24.05.2017
17	Daclatasvir Tablet 60 mg	"For use with Sofosbuvir for the treatment of patients with chronic hepatitis C virus (HCV) genotype 3 infection". **With the condition: to be sold by retail on the prescription of Hepatologist only**	24.05.2017
18	Rosuvastatin Tablets 15 mg	a. Treatment of patients with primary hypercholesterolemia or mixed dyslipedemia, homozygous familial hyper cholesterolemia as an adjutant to diet,when response to diet and excercise isinadequate b. As an adjunctive therapy to diet for the treatment of adult patients with hypertriglycerdemia. c. As an adjunctive therapy to diet to slow the progression of atherosclerosis in adult patients as part of a treatment strategy to lower total C and LDL-C to targetlevels. d. Risk reduction of Myocardial Infarction stroke and arterial revascularization procedure in patients without clinically evident CHD but with multiple risk factors. e. As an adjunct to diet for the treatment of patients with primary dysbetalipoproteinemia (type-III hyperlipoprotenemia). f. As adjunct to diet to reduce total-C,LDL-C and ApoB levels in adolescent boys and girls,who are atleast one year post-menarche,10-17 years of age with heterozygous familial hypercholesterolemia if after and adequate trial of diet therapy the following findings are present:LDL-C >190 mg/dL or > 160 mg/dL and there is a positive family history of premature cardiovascular disease (CVD) or two or more CVD riskfactors.	30.05.2017
19	Rosuvastatin film coated Tablets 30 mg	a. Treatment of patients with primary hyper cholesterolemia or mixed dyslipedemia, homozygous familial hyper cholesterolemia as an adjutant to diet,when response to diet and excercise isinadequate b. As an adjunctive therapy to diet for the	30.05.2017

		treatment of adult patients with hypertriglycerdemia. c. As an adjunctive therapy to diet to slow the progression of atherosclerosis in adult patients as part of a treatment strategy to lower total C and LDL-C to targetlevels. d. Risk reduction of Myocardial Infarction stroke and arterial revascularization procedure in patients without clinically evident CHD but with multiple risk factors. e. As an adjunct to diet for the treatment of patients with primary dysbetalipoproteinemia (type-III hyperlipoprotenemia). f. As adjunct to diet to reduce total-C, LDL-C and ApoB levels in adolescent boys and girls, who are atleast one year post-menarche,10-17 years of age with heterozygous familial hypercholesterolemia if after and adequate trial of diet therapy the following findings are present:LDL-C >190 mg/dL or > 160 mg/dL and there is a positive family history of premature cardiovascular disease (CVD) or two or more CVD riskfactors.	
20	Abiraterone Acetate Tablet 500 mg	1. In combination with prednisone for the treatment of patients with metastatic castration resistant prostate cancer who have received prior chemotherapy containing docetaxel 2. For the treatment of metastatic castration resistant prostate cancer in adult men who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated with prednisone orprednisolone. **With the condition: to be sold by retail on the prescription of Oncologist only**	12.07.2017
21	Enzalutamide hard Gelatin Capsules 40 mg	For the treatment of adults with metastatic castration resistant prostate cancer whose disease has progressed on or after Docetaxel therapy. **With the condition: to be sold by retail on the prescription of Oncologist only**	12.07.2017

FDA BANNED DRUG LIST

Date	Drug	Reason	Company
08/09/2017	Pravastatin Sodium Tablets	Labeled as Pravastatin Sodium Tablets USP 40 mg but contained Bupropion Hydrochloride XL 300 mg tablets	International Laboratories, LLC
08/02/2017	Diocto Liquid and Diocto Syrup	Potential contamination with Burkholderiacepacia	Rugby® Laboratories
07/28/2017	0.9% Sodium Chloride Injection, USP 1000 ml	Particulate matter	ICU Medical, Inc.
07/27/2017	Cyclobenzaprine HCl Tablet and Amantadine HCl Capsule	Cyclobenzaprine HCL may contain Amantadine HCL Capsules	Apace Packaging LLC
07/11/2017	Sten Z and M1 Alphas capsules	Unapproved drug	Andropharm
06/23/2017	Succinylcholine Chloride 20mg/mL	Lack of Sterility Assurance	Fagron Sterile Services
06/22/2017	Potassium Phosphate and Succinylcholine Chloride	Lack of Sterility Assurance	Advanced Pharma, Inc. d/b/a Avella of Houston
06/17/2017	Eliquis (apixaban) 5 mg Tablets	Tablet Mix-Up	Bristol-Myers Squibb
06/16/2017	Clindamycin Injection USP	Lack of sterility assurance	Alvogen
06/15/2017	8.4% Sodium Bicarbonate Injection, USP, NeutTM (Sodium Bicarbonate 4% additive solution), QUELICINTM (Succinylcholine Chloride Injection, USP) and Potassium Phosphates Injection, USP	Lack of Sterility Assurance	Hospira Inc, A Pfizer Company
06/15/2017	Nitroglycerin products	Due to sub-potency	Advanced Pharma, Inc. d/b/a Avella of Houston
06/15/2017	Paliperidone Extended-Release Tablets, 3mg	Potential for product to be below specification	Teva Pharmaceuticals USA, Inc
06/10/2017	Eliquis (apixaban) 5 mg Tablets	Tablet Mix-Up	Bristol-Myers Squibb
05/25/2017	professional (physician) sample BRILINTA (ticagrelor) 90mg tablets	Product container contained another medicine called ZURAMPIC	Astrazeneca
05/25/2017	Mibelas 24 Fe (Norethindrone Acetate and Ethinyl Estradiol 1 mg/0.02 mg chewable and ferrous fumarate 75 mg)	Out of Sequence Tablets and Missing Expiry/Lot information	Lupin Pharmaceuticals Inc.
05/08/2017	Amitriptyline HCL Tablets, USP 50mg and Phenobarbital Tablets, USP 15mg, 30mg, 60mg, 100mg	Labeling mix-up	C.O. Truxton, Inc.
04/21/2017	25% Dextrose Injection, USP (Infant)	Particulate matter (human hair)	Hospira, Inc.
04/21/2017	Phenobarbital Tablets, USP, 15 mg	Product may contain 30 mg tablets	C.O. Truxton, Inc.
03/31/2017	EpiPen (epinephrine injection, USP) and EpiPen Jr® (epinephrine injection, USP) Auto-Injectors	Failure to activate the device due to a potential defect	Mylan N.V.
02/24/2017	Alprostadil for injection	Potential Lack of Sterility Assurance	Endo Pharmaceuticals Inc.
02/14/2017	Human Chorionic Gonadotropin (HCG) for injection	Lack of Sterility Assurance	Synergy Rx Pharmacy
02/08/2017	Ibuprofen Lysine Injection, 20 mg/2 mL	Presence of particulate matter	Exela Pharma Sciences, LLC
01/24/2017	Vancomycin Hydrochloride for injection	Particulate matter	Hospira, Inc.

CURRENT TRENDS IN MEDICAL SCIENCE

ROBOTIC SURGERY

Robotic surgery use robotic systems to aid in surgical procedures. Robotically-assisted surgery was developed to overcome the limitations of pre-existing minimally-invasive surgical procedures and to enhance the capabilities of surgeons performing open surgery.

In the case of robotically-assisted minimally-invasive surgery, instead of directly moving the instruments, the surgeon uses one of two methods to control the instruments; either a direct telemanipulator or through computer control. A telemanipulator is a remote manipulator that allows the surgeon to perform the normal movements associated with the surgery whilst the robotic arms carry out those movements using end-effectors and manipulators to perform the actual surgery on the patient. In computer-controlled systems the surgeon uses a computer to control the robotic arms and its end-effectors, though these systems can also still use telemanipulators for their input. One advantage of using the computerised method is that the surgeon does not have to be present, but can be anywhere in the world, leading to the possibility for remote surgery.

In the case of enhanced open surgery, autonomous instruments (in familiar configurations) replace traditional steel tools, performing certain actions (such as rib spreading) with much smoother, feedback-controlled motions than could be achieved by a human hand. The main object of such smart instruments is to reduce or eliminate the tissue trauma traditionally associated with open surgery without requiring more than a few minutes' training on the part of surgeons. This approach seeks to improve open surgeries, particularly cardiothoracic, that have so far not benefited from minimally-invasive techniques.

Advantages over traditional methods: Major advances aided by surgical robots have been remote surgery, minimally invasive surgery and unmanned surgery. Due to robotic use, the surgery is done with precision, miniaturization, smaller incisions; decreased blood loss, less pain, and quicker healing time. Articulation beyond normal manipulation and three-dimensional magnification helps resulting in improved ergonomics. Due to these techniques there is a reduced duration of hospital stays, blood loss, transfusions, and use of pain medication. The existing open surgery technique has many flaws like limited access to surgical area, long recovery time, long hours of operation, blood loss, surgical scars and marks.

Compared with other minimally invasive surgery approaches, robot-assisted surgery gives the surgeon better control over the surgical instruments and a better view of the surgical site. In addition, surgeons no longer have to stand throughout the surgery and do not tire as quickly. Naturally occurring hand tremors are filtered out by the robot's computer software. Finally, the surgical robot can continuously be used by rotating surgery teams.

Limitations: The robot normally costs $1,390,000 and while its disposable supply cost is normally $1,500 per procedure, the cost of the procedure is higher. Additional surgical training is needed to operate the system. Numerous feasibility studies have been done to determine whether the purchase of such systems are worthwhile. As it stands, opinions differ dramatically. Surgeons report that, although the manufacturers of such systems provide training on this new technology, the learning phase is intensive and surgeons must operate on twelve to eighteen patients before they adapt. During the training phase, minimally invasive operations can take up to twice as long as traditional surgery, leading to operating room tie ups and surgical staffs keeping patients under anesthesia for longer periods. Patient surveys indicate they chose the procedure based on expectations of decreased morbidity, improved outcomes, reduced blood loss and less pain. Higher expectations may explain higher rates of dissatisfaction and regret.

Critics of the system, including the American Congress of Obstetricians and Gynecologists, say there is a steep learning curve for surgeons who adopt use of the system and that there's a lack of studies that indicate long-term results are superior to results following traditional laparoscopic surgery.

General surgery: In early 2000 the field of general surgical interventions with the daVinci device was explored by surgeons at Ohio State University. Reports were published in esophageal and pancreatic surgery for the first time in the world and further data were subsequently published by Horgan and his group at the University of Illinois and then later at the same institution by others. In 2007, the University of Illinois at Chicago medical team, led by Prof. Pier Cristoforo Giulianotti, reported a pancreatectomy and also the Midwest's first fully robotic Whipple surgery. In April 2008, the same team of surgeons performed the world's first fully minimally invasive liver resection for living donor transplantation, removing 60% of the patient's liver, yet allowing him to leave the hospital just a couple of days after the procedure, in very good condition. Furthermore, the patient can also leave with less pain than a usual surgery due to the four puncture holes and not a scar by a surgeon.

Cardiothoracic surgery: Robot-assisted MIDCAB and Endoscopic coronary artery bypass (TECAB) operations are being performed with the Da Vinci system. Mitral valve repairs and replacements have been performed. The Ohio State University, Columbus has performed CABG, mitral valve, esophagectomy, lung resection, tumor resections, among other robotic assisted procedures and serves as a training site for other surgeons. In 2002, surgeons at the Cleveland Clinic in Florida reported and published their preliminary experience with minimally invasive "hybrid" procedures. These procedures combined robotic revascularization and coronary stenting and further expanded the role of robots in coronary bypass to patients with disease in multiple vessels

Colon and rectal surgery: Results to date indicate that robotic-assisted colorectal procedures outcomes are "no worse" than the results in the now "traditional" laparoscopic colorectal operations. Robotic-assisted colorectal surgery appears to be safe as well. Most of the procedures have been performed for malignant colon and rectal lesions. However, surgeons are now moving into resections for diverticulitis and non-resective

Gastrointestinal surgery: Multiple types of procedures have been performed with either the 'Zeus' or da Vinci robot systems, including bariatric surgery and gastrectomy for cancer. Surgeons at various universities initially published case series demonstrating different techniques and the feasibility of GI surgery using the robotic devices. Specific procedures have been more fully evaluated, specifically esophageal fundoplication for the treatment of gastroesophageal reflux and Heller myotomy for the treatment of achalasia.Other gastrointestinal procedures including colon resection, pancreatectomy, esophagectomy and robotic approaches to pelvic disease have also been reported.

Gynecology: Robotic surgery in gynecology is of uncertain benefit with it being unclear if it affects rates of complications. Gynecologic procedures may take longer with robot-assisted surgery but may be associated with a shorter hospital stay following hysterectomy. Robotic surgery can be used to treat fibroids, abnormal periods, endometriosis, ovarian tumors, uterine prolapse, and female cancers. Using the robotic system, gynecologists can perform hysterectomies, myomectomies, and lymph node biopsies.

Neurosurgery: Several systems for stereotactic intervention are currently on the market. The NeuroMate was the first neurosurgical robot, commercially available in 1997. IMRIS Inc.'s SYMBIS(TM) Surgical System will be the version of NeuroArm, the world's first MRI-compatible surgical robot, developed for world-wide commercialization

Ophthalmology: The first robotic operation inside the eye took place at the John Radcliffe Hospital in Oxford on 9 September 2016. The robot was developed by Preceyes BV and the surgery was performed by Robert MacLaren, Professor of Ophthalmology at the University of Oxford. They operated successfully on the Reverend Dr William Beaver, a 70 year old man with a macular hole. The researchers commented that robotic eye surgery has taken longer to develop due to the need to miniaturise the components. They observed that the robot could make controlled movements inside the eye as small as 100th of a millimetre.

Orthopedics: The Acrobot Company Ltd.developed the "Acrobot Sculptor", a robot that constrained a bone cutting tool to a pre-defined volume. Another example is the CASPAR robot produced by U.R.S.which is used for total hip replacement, total knee replacement and anterior cruciateligament reconstruction. MAKO Surgical Corp (founded 2004) produces the RIO (Robotic Arm Interactive Orthopedic System) which combines robotics, navigation, and haptics for both partial knee and total hip replacement surgery The Navio System is a navigated, robotics-assisted surgical system that uses a CT free approach to assist in partial knee replacement surgery.

Children: Surgical robotics has been used in many types of pediatric surgical procedures including: tracheoesophageal fistula repair, cholecystectomy, nissen fundoplication, morgagni's hernia repair, kasai portoenterostomy, congenital diaphragmatic hernia repair, and others.

Transplant surgery: The development of robotic technology and its associatedhigh resolution capabilities, three dimensional visual system, wrist type motionand fine instruments, gave opportunity for highly complex procedures to be completed in a minimally invasive fashion. Subsequently, the first fully robotic kidney transplantations were performed in the late 2000s. Due to the abundantly higher risk of complications after traditional open kidney transplantation, obese patients were frequently denied access to transplantation, which is the premium treatment for end stage kidney disease. The use of the robotic-assisted approach has allowed kidneys to be transplanted with minimal incisions, which has virtually alleviated wound complications and significantly shortened the recovery period.

Urology: Robotic surgery in the field of urology has become very popular, especially in the United States. It has been most extensively applied for excision of prostate cancer because of difficult anatomical access. It is also utilized for kidney cancer surgeries and to lesser extent surgeries of the bladder.

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