Vol. 23 July - September 2021

# Newsletter of Drug Information and Research Center, KSPC



Member of International Society of Drug Bulletins (ISDB)

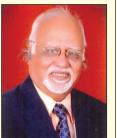
# Official Desk



Dear Pharmacists,

Distribution of Apron, Nameplate and Key chain for the Registered Pharmacists in the State of Karnataka

Karnataka State Pharmacy Council has initiated distribution of Apron, Name Plate and Key Chain for the Registered Pharmacists who are working in retail or hospital Pharmacy and Academician in Colleges across Karnataka. This distribution is carried out in association with the Pharmacy Colleges, Deputy Drugs Controller, Assistant



Drugs Controller & Drug Inspectors of the respective division, and the various Hospital /Clinical/Govt. Pharmacist Associations.

The main objective of this distribution is to help the Pharmacy Colleges to establish a contact within the respective district Registered Pharmacists, so that the students from colleges can be trained under the qualified Pharmacist near to the college. The Registered Pharmacist also will be recognized by the public or customer and this will improve the image of the Pharmacy Profession and Pharmacists in society.

Finally, our Pharmacy profession and the services rendered by the Pharmacists for the society or public should get recognized by the Government.

# **Guest Column** Pharmacist enhances efficacy of prescription

Medication errors and patient compliance problems are two major reasons that substantially cause treatment failures and adverse events. These lead to revisits, hospitalization, loss of productive man hours and economic pressure. In between the prescribing physician and patient under treatment; Pharmacist is in a unique position to safeguard public health by careful audit of the prescription to ensure rational therapy and rational use of medicines; accurate dispensing of the medicines

prescribed, adequate patient counseling to ensure patient compliance and medication adherence. These intricacies of correctly following the medical advice ensure intended benefits of the prescription and safeguard from untoward effects. The dose of medicine, frequency of administration, route of administration



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# Dr. R. S. Thakur

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and duration of treatment is based on pharmacokinetic profile of the drug and hence, any deviation in those leads to either sub-therapeutic level or overdosing. In other words leads to treatment failure or toxicity. This explains the importance of patient counseling while dispensing the prescription.







There are many reasons for medication errors: poor handwriting, prescribing brand names instead of generic name, medicine shops run by unqualified persons, ease of availability of prescription only medicines without prescription, self-medication, abundance of quacks, Look Alike Sound Alike (LASA) brand names of medicines, lack of awareness about medicines and trade interests in the business of medicines at the cost of health and happiness of citizens.

Mr. Chilukuri Paramathma, a diploma pharmacist from Nalgonda, Telangana State, seriously took up issue of illegible prescription through legal forum, State and Central government and the Medical Council of India. His efforts resulted in amendment of the "Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002" by substituting clause 1.5 in Chapter 1-B-Duties and responsibilities of the Physician in general, vide notification in the Gazette of India Extraordinary, part III - Section 4, No. 366 dated October 8, 2016 which is reproduced below:

"Every physician should prescribe drugs with generic names legibly and preferably in capital letters and he/ she shall ensure that there is a rational prescription and use of drugs"

However, one can hardly find a prescription having generic name of drugs and written in capital letters. The issue of rational prescription and rational use of drugs is another alarming situation to improve safety and efficacy of medication. The the prevailing situation demands that governments of welfare nations must realize the pathetic plight of patients who are forced to consume whatever is illegibly prescribed to them and without ascertaining exactly what is prescribed sold to them by traders of medicines. This practice harms public health to a great extent. Increased sufferings of the patients, medicine induced diseases and even deaths do occur, but not reported at all. By any means can it be said public welfare!

By grossly ignoring the important role of pharmacist in ensuring avoidance of medication error, strict adherence to medication regimen and guarantee of right medicine to the right patient in right dose at right intervals by right route of administration up to the right duration of therapy; patients are simply denied rational treatment and compulsorily exposed to untoward effects of medicines. The whole plight of healthcare without appropriate pharmaceutical care is highly injurious to public health, national economy, industrial growth and health and happiness of citizens. Sooner Governments awake is better in larger public interest. Safe and effective medication is every patient's right.

# Drug of the Quarter

Drug : Cariprazine

Class : Antipsychotic

: Capsules Strength : 1.5mg/3mg/4.5mg and 6mg

: 16<sup>th</sup> July 2021 DCGI Approval **USFDA Approval**: September 2015

Indication: Treatment of Schizophrenia in adults. Acute treatment of manic or mixed episodes associated with bipolar I disorder in adults.

# **Dosing Information:**

**Dosing Form** 

### Adult:

# Bipolar I disorder, Acute mixed or manic episodes

- Initial, 1.5 mg orally once daily on day 1; increase to 3 mg once daily on day 2 and adjust dose in 1.5- or 3-mg increments thereafter based upon clinical response and tolerability; MAX 6 mg once daily
- Maintenance, 3 to 6 mg orally once daily

### Depressed bipolar I disorder

Initial, 1.5 mg orally once daily; may increase to 3 mg once daily on day 15 based upon clinical response and tolerability; MAX, 3 mg once daily

### Schizophrenia

- Initial, 1.5 mg orally once daily on day 1; may increase to 3 mg once daily on day 2 and adjust dose in 1.5- or 3-mg increments thereafter based on clinical response and tolerability; MAX 6 mg once daily
- Maintenance, 1.5 to 6 mg orally once daily

#### **Pharmacokinetics**

# **Absorption**

- Tmax, Oral: 3 to 6 hours
- Effect of Food: No significant effect on AUC or Cmax of cariprazine or the metabolite DCAR

# Distribution

Protein binding, cariprazine and its major active metabolites: 91% to 97%

# Metabolism

- Hepatic: Extensive, by CYP3A4
- Metabolite, desmethyl cariprazine (DCAR), major: Active
- Metabolite, didesmethyl cariprazine (DDCAR), major: Active
- Substrate of CYP3A4







#### **Excretion**

Renal: 21% (1.2% unchanged)

#### **Elimination Half Life**

Cariprazine: 2 to 4 days

Desmethyl cariprazine (DCAR): 1 to 2 days

 Didesmethyl cariprazine (DDCAR): 1 to 3 weeks; variable across patients

### **Contraindications:**

• History of a hypersensitivity reaction to cariprazine.

#### **Cautions:**

- Cardiovascular: Orthostatic hypotension and syncope may occur, especially during initial dose titration, dosage increases, and in patients with known cardiovascular disease, monitoring recommended for at risk patients.
- ➤ **Hematologic:** May increase risk of bleeding in patients with bleeding disorders or active peptic ulceration.
- Endocrine and Metabolic: Hyperglycemia, metabolic changes, disruption of body temperature regulation has been reported with atypical antipsychotic use; monitoring recommended.
- Hematologic: Fatal agranulocytosis, Leukopenia and neutropenia have been reported, monitoring recommended and discontinuation may be required.

## Neurologic:

 Seizures may occur; use caution in patients with a history of seizures, the elderly, or with conditions that lower seizure threshold.  Potential cognitive and motor impairment may affect how patients operate machinery or motor vehicles; caution advised until drug effects are known.

### Mechanism of Action

Although the exact mechanism of action of cariprazine, an atypical antipsychotic, in schizophrenia and bipolar I disorder is unknown, it is a partial agonist of serotonin 5-HT-1A activity and dopamine D2 receptors, and antagonist of serotonin 5-HT-2A activity.

### **Adverse Effects**

#### Common

- Gastrointestinal: Indigestion, Vomiting
- Neurologic: Akathisia, Extrapyramidal sign, Somnolence
- **Psychiatric:** Restlessness

### Serious

- Cardiovascular: Ischemic stroke, Orthostatic hypotension
- Endocrine metabolic: Diabetes mellitus, Dyslipidemia, Hyperglycemia
- Gastrointestinal: Esophageal dysmotility
- Hematologic: Leukopenia, Neutropenia
- Musculoskeletal: Tardive dyskinesia
- Neurologic: Seizure
- Psychiatric: Loss of judgement, Suicidal thoughts
- Respiratory: Pulmonary aspiration
- Other: Body temperature finding, Body temperature dysregulation, Neuroleptic malignant syndrome

# **Drug-Drug Interactions**

Category	Drug/s (Examples)	Interaction Effect	Management
Antiemetic*	Metoclopramide	May result in increased risk of extrapyramidal reactions and neuroleptic malignant syndrome.	Contraindicated for concurrent use.
Dopamine Antagonist*	Bromopride	May result in increased risk of extrapyramidal reactions.	Contraindicated for concurrent use.
Strong CYP3A4 Inhibitors *	Carbamazapine, Clarithromycin, Ketoconazole, Itraconazole, Fosphenytoin, Lopinavir	May increase the plasma concentrations of both cariprazine and its active metabolite, didesmethylcariprazine.	Avoid concomitant use.
Analgesic**	Methadone	May result in increased risk of respiratory and CNS depression.	Avoid concomitant use.
Analgesic**	Buprenorphine	May result in increased risk of respiratory and CNS depression.	Avoid concomitant use.

**Severity:** \*The drugs are contraindicated for concurrent use. \*\*The interaction may be life-threatening and/or require medical intervention to minimize or prevent serious adverse effects.







# **Effects in Pregnancy**

Severity	Management
Moderate	Fetal risk cannot be ruled out. Available evidence is inconclusive or is inadequate for determining fetal risk when
	Cariprazine is used in pregnant women or women of childbearing potential. Weigh the potential benefits of drug
	treatment against potential risks before prescribing Cariprazine during pregnancy.

### **Effect in Lactation**

Severity	Management
Major	Infant risk cannot be ruled out. Available evidence and/or expert consensus is inconclusive or is inadequate for determining
	infant risk when Cariprazine is used during breast-feeding. Weigh the potential benefits of treatment against potential
	risks before prescribing Cariprazine during breast-feeding.

### **Patient Education:**

- 1. Advise diabetic patient to monitor for symptoms of hyperglycemia and report difficulties with glycemic control.
- 2. Advise patient to report symptoms of hypotension with initial dosing and dose changes

### **References:**

- 1. http://www.micromedexsolutions.com/
- 2. http://www.cdsco.nic.in/
- 3. https://www.drugs.com/

# Drug Safety Alerts - Pharmacovigilance Programme of India (PvPI)



The preliminary analysis of Serious Unexpected Serious Adverse Reaction (SUSARs) from the PvPI database reveals that the following drugs are associated with the risks as given below.

SI. No	Suspected Drug/s	Category	Indication/Use	Adverse Reaction/s Reported		
	July 2021					
1	Inhibitor inflammatory conditions due to arthritis.		Acute Generalized Exanthematous Pustulosis (AGEP).			
2	Torsemide	Diuretic	Treatment of oedema associated with congestive heart failure & hypertension.	DRESS Syndrome.		
3	Quetiapine & Valproic Acid Interaction  Antipsychotic & Anticonvulsant   Quetiapine: Used for the management of the manifestation of psychotic disorders (schizophrenia) as well as for "acute manic episode associated with bipolar disorder".  Valproic Acid: As monotherapy and adjunctive therapy in the treatment of patients with complex partial seizures that occur either in isolation or in association with other types of seizure.		Neuropsychiatric Adverse Events (Depressed level of consciousness / Coma & Disorientation)			
			June 2021			
1	Clobazam	Anticonvulsant	Treatment of acute and chronic anxiety states and as an adjunctive therapy in patients with refractory epilepsy.	DRESS Syndrome		
2	Baclofen Analgesic Used for the symptomatic treatment of neuronal spasticity due to multiple sclerosis, spinal cord, pathology & injury.		Encephalopathy			
3	Rosuvastatin & Ticagrelor Interaction	Antihyperlipidemic & Blood Modifier Agent	Rosuvastatin: Used to reduce the risk reduction of MI stroke and arterial revascularization procedure in patients without clinically evident CHD but with multiple risk factors.	Rhabdomyolysis		







SI. No	Suspected Drug/s	Category	Indication/Use	Adverse Reaction/s Reported
			Ticagrelor: Used for the prevention of thrombotic events (cardiovascular death, Myocardial Infarction and stroke) in patients with Acute Coronary Syndromes (ACS) unstable angina, non ST Elevation Myocardial Infarction (STEMI) including patients managed medically and those who are managed with Percutaneous Coronary Intervention (PCI) or Coronary Artery Bypass Grafting (CABG).	
April 2021				
	Zinc (Acetate/ Oxide/ Sulphate/ Glu conate)	Nutritive Agent	Treatment of acute diarrhoea in children as an adjunct to oral rehydration.	Diarrhoea

Healthcare professionals, Patients / Consumers are advised to closely monitor the possibility of the above adverse events associated with the use of above drugs.

If such events are encountered, please report to the NCC-PvPI either by filling of Suspected Adverse Drug Reactions Reporting Form/Medicines Side Effect Reporting Form for Consumer (http://www.ipc.gov.in) or by PvPI Helpline No. 1800-180-3024.

## Meaning: Acute Generalized Exanthematous Pustulosis -

A severe, usually drug-related reaction, characterized by an acute onset of mainly small non-follicular pustules on an erythematous base and spontaneous resolution usually withing two weeks, **Rhabdomyolysis**- a serious syndrome due to a direct or indirect muscle injury.

Reference: www.ipc.gov.in

# Serious Risks/Safety Information – USFDA

# Potential Signals of Serious Risks/New Safety Information Identified by the Adverse Event Reporting System (AERS) – USFDA

The USFDA Adverse Event Reporting System (FAERS) is a database that contains information on adverse event and medication error reports submitted to FDA. The database is designed to support the FDA's post-marketing safety surveillance program for drug and therapeutic biologic products.

The appearance of a drug on this list does not mean that

conclusive of the risk. It means that FDA has identified a *potential safety issue* but does not mean that FDA has identified a causal relationship between the drug and the listed risk. If after further evaluation the FDA determines whether the drug is associated with the risk or not and it may take a variety of actions including requiring changes to the labeling of the drug, requiring development of a Risk Evaluation and Mitigation Strategy (REMS) or gathering additional data to better characterize the risk.

Therapeutic Class / Category	Drug (Examples)	Route of Administration	Potential Signal of a Serious Risk / New Safety Information	Additional Information (as of March 23, 2021)
	Octobe	r - December 202	0	
Analgesic	Acetaminophen	Intravenous/ Oral/ Rectal	Stevens-Johnson Syndrome	Evaluation in progress.
Antimigraine	Fremanezumab, Eptinezumab	Intravenous	Anaphylactic reaction	Evaluation in progress.
Antineoplastic Agent	Brigatinib, Crizotinib, Fremanezumab, Ceritinib	Oral	Photosensitivity reaction	Evaluation in progress.
Antineoplastic Agent	Aminolevulinic acid hydrochloride, 5-aminolevulinic acid hydrochloride, Methyl aminolevulinate hydrochloride	Topical	Hypersensitivity	Evaluation in progress.







Therapeutic Class / Category	Drug (Examples)	Route of Administration	Potential Signal of a Serious Risk / New Safety Information	Additional Information (as of March 23, 2021)
Anti-Infective Agent	Benznidazole, Fexinidazole, Metronidazole, Secnidazole, Tinidazole	Oral	Hepatic failure	Evaluation in progress.
Antidiabetic	Dapagliflozin, Empagliflozin and linagliptin, Canagliflozin, Saxagliptin and dapagliflozin, Dapagliflozin and metformin	Oral	Diabetic ketoacidosis in patients with Type 1 diabetes mellitus	Evaluation in progress.
Antineoplastic Agent	Enfortumab vendotin	Intravenous	Stevens-Johnson Syndrome	Evaluation in progress.
Antineoplastic Agent	Alpelisib	Oral	Colitis	Evaluation in progress.
Immunological Agent	Denosumab	Subcutaneous	Hypersensitivity vasculitis	Evaluation in progress.
Antineoplastic Agent	Isatuximab	Intravenous	Anaphylactic reaction	Evaluation in progress.

# **References:**

- 1. http://www.fda.gov/
- 2. www.micromedexsolutions.com, Micromedex (R) 2.0, 2002-2021, IBM Corporation 2021.

# Drug News - Around the Globe



1. Drug: Ropeginterferon alfa-2b\* Country: USA

Ropeginterferon alfa-2b is an interferon.

**Approved Indication:** Ropeginterferon alfa-2b is approved injection to treat adults with polycythemia vera, a blood disease that causes the overproduction of red blood cells. The excess cells thicken the blood, slowing blood flow and increasing the chance of blood clots.

Ropeginterferon alfa-2b is the first FDA-approved medication for polycythemia vera that patients can take regardless of their treatment history, and the first interferon therapy specifically approved for polycythemia vera.

Approved Dosage Form: Subcutaneous.

**Side-effects:** Liver enzyme elevations, low levels of white blood cells, low levels of platelets, joint pain, fatigue, itching, upper airway infection, muscle pain and flu-like illness<sup>1</sup>.

2. Drugs: Evolocumab\*\* Country: USA

Evolocumab is an Antihyperlipidemic agent.

**Approved Indication:** Evolocumab is approved as an addon treatment to diet alone or together with certain other therapies for patients aged 10 years and older with heterozygous familial hypercholesterolemia (HeFH) and homozygous familial hypercholesterolemia (HoFH).

Approved Dosage Form: Subcutaneous.

**Side-effects:** Nasopharyngitis (cold), headache, oropharyngeal pain (sore throat) and upper respiratory tract infection<sup>1</sup>.

3. Drugs: Paliperidone palmitate\*\* Country: USA

Paliperidone palmitate an atypical antipsychotic.

**Approved Indication:** Paliperidone palmitate is approved to treat schizophrenia in certain adults. This is the first long-acting schizophrenia medication to be injected once every six months.

Approved Dosage Form: Intramuscular.

**Side-effects:** Upper respiratory tract infection, injection site reaction, weight gain, headache, and movement abnormalities<sup>1</sup>.

4. Drugs: Vosoritide\* Country: USA

Vosoritide is a C-Type Natriuretic Peptide Analogue.

**Approved Indication:** Vosoritide is approved to improve growth in children five years of age and older with achondroplasia and open epiphyses (growth plates), meaning these children still have the potential to grow. Achondroplasia is the most common form of dwarfism. Vosoritide is the first FDA approved treatment for children with achondroplasia.

Approved Dosage Form: Injection.

**Side-effects:** Injection site reactions, vomiting and decreased blood pressure<sup>1</sup>.

Note – \*Not available in India.

\*\*Available in India

Reference: https://www.fda.gov/







# **Continuing Pharmacy Education (CPE)**

# Dispensing Instructions to the Pharmacists

Asthma-Drug Therapy - Continuation from the previous newsletter issue

# (Oral/Inhalation/Nasal spray)

Drugs/ Category	Use	Warnings	Less serious side effects	Advice
Mometasone Dosage forms: Inhalation	Indicated for maintenance treatment of asthma as prophylactic therapy.	Prescription to be reconfirmed in case of patient is pregnant or breastfeeding or have osteoporosis, vision problems (including cataracts, glaucoma), glaucoma or any type of infection, especially a lung infection such as tuberculosis.	Headache, nasal discomfort or nosebleed, musculoskeletal pain.	Advice the patient to use drug at regular intervals and to contact physician if improvement is not seen within 2 weeks after starting therapy.  Advise patient that drug is not indicated for acute asthma attacks and to report asthma episodes that are not responsive to bronchodilators.  Advice patient using oral inhaler to rinse mouth with water (do not swallow) after use to prevent oral infections.  Advise patient that the inhalation aerosol is not indicated for acute asthma attacks.  Advice patients to use the medicine exactly as directed by their physician.  Advice patient to rinse mouth with water without swallowing after use to reduce
Montelukast Dosage forms:	Used for the prophylaxis	Prescription to be reconfirmed in case of	Headache, cough, pain in throat,	risk of oral candidiasis.  Advise patient against sudden discontinuation of drug.  Advice patient on proper administration technique. Avoid direct contact with nasal septum or eyes.  Advise patient that drug is not indicated for acute asthma attacks and to report
Oral	and chronic treatment of asthma.	patient is pregnant or breastfeeding, or if you have liver disease or history of depression or mental health problems.	abdominal pain, diarrhea.	asthma episodes that are not responsive to bronchodilators.  Advise patient to continue with other asthma medications as prescribed unless instructed by a healthcare professional.  Advice the patient who misses a dose to take the next dose at regular time and to avoid taking 2 doses at the same time.

(to be continued.....)

**Storage:** Advice the patient or caretaker to store the medicine in a closed container at room temperature, away from heat, moisture, and direct light. Ensure to keep all medicine out of the reach of children.

#### References:

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- 1. Handbook of Pharma SOS, Educational Series-I, 9th Edition 2020, published by Karnataka State Pharmacy Council, Bangalore.
- 2. www.micromedexsolutions.com, Micromedex® 2.0,2002-2021, IBM Corporation 2021.
- 3. www.mayoclinic.org

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# Drug Usage in Special Population - Pediatrics and Geriatrics

### (From KSPCDIRC publication)

#### **Anticoagulants**

Drug	Usage in Children (Pediatrics)	Usage in Elderly (Geriatrics)	
Nadroparin	Safety and efficacy have not been established. Dose adjustment requires in renal impairment.		
Vitamin K Phytonadione	Safety and efficacy have been established.	No dosage adjustment required.	
Protamine Sulphate	Safety and efficacy have not been established.	shed. No geriatric guidelines available.	
Warfarin	Safety and efficacy have not been established.	Dosage adjustment not required. But close monitoring	
		required.	

**Reference:** Drug Usage in special Population-Pediatrics and Geriatrics, Educational Series-II, 9<sup>th</sup>Edition 2020, published by Karnataka State Pharmacy Council, Bengaluru.

# Drug Usage in Special Population - Pregnancy and Lactation

### (From KSPCDIRC publication)

### **Anticoagulants**

Drug	Usage in Pregnancy (Teratogenicity)	Usage in Breastfeeding (Lactation)
Nadroparin	Fetal risk cannot be ruled out. Use with caution.	Data not available.
Vitamin K	Fetal risk cannot be ruled out. Available evidence is inconclusive or is	Infant risk cannot be ruled out.
(Phytonadione)	inadequate for determining fetal risk when used in pregnant women	Use with Caution.
	or women of childbearing potential.	
Protamine Sulphate	Fetal risk cannot be ruled out. Use only during pregnancy if the	Infant risk cannot be ruled out.
	potential benefit justifies the potential risk to the fetus.	Not recommended.
Warfarin	Contraindicated	Compatible with breastfeeding.

**Reference:** Drug Usage in special Population-Pregnancy and Lactation, Educational Series-I, 8<sup>th</sup> Edition 2020, published by Karnataka State Pharmacy Council, Bangalore.

# ಭೇಷಜೀ ಪರಿಕರ್ಮ ನಿಬಂಧನೆಗಳು, 2015 (Pharmacy Practice Regulation, 2015)

(ಅಧ್ಯಾಯ-4)

# 9. ನೋಂದಾಯಿತ ಭೇಷಜಜ್ಞರ ಕರ್ತವ್ಯಗಳು:

## 9.1 ಔಷಧಗಳ ವಿನಿಯೋಗ / ಸರಬರಾಜು:

- (ಎ) ಮೊಟ್ಟನದಿಂದ ಔಷಧಿ ತೆಗೆಯುವುದು, ವೈದ್ಯಲಿಖಿತದಲ್ಲಿನ ಔಷಧಿ ತುಂಬಿಕೊಡುವುದು ಇತ್ಯಾದಿ ಔಷಧ ವಿನಿಯೋಗದ ವಿವಿಧ ಚಟುವಟಿಕೆಗಳನ್ನು ಒಬ್ಬ ನೋಂದಾಯಿತ ಭೇಷಜಜ್ಞರ ವೈಯಕ್ತಿಕ ವೇಲ್ವಿಚಾರಣೆಯಲ್ಲಿ, ಈ ಕಾರ್ಯಗಳನ್ನು ನೆರವೇರಿಸಲು ತರಬೇತಿ ಪಡೆದ ಯಾವುದೇ ವ್ಯಕ್ತಿ ನಿರ್ವಹಿಸಬಹುದು. ಇತರರಿಂದ ತುಂಬಿಸಲ್ಪಟ್ಟ ವೈದ್ಯಲಿಖಿತದ ಔಷಧವನ್ನು ರೋಗಿಗೆ ವಿನಿಯೋಗಗೊಳಿಸುವ ನಿಜವಾದ ಕರ್ತವ್ಯವು ವೈದ್ಯಲಿಖಿತದ ಅಧಿಕೃತ ತುಲನೆಯ ನಂತರ, ನೋಂದಾಯಿತ ಭೇಷಜಜ್ಞರಿಂದ ಮಾತ್ರ ನಿವಾಹಿಸಲ್ಪಡತಕ್ಕದ್ದು,
- (ಬಿ) ವಿನಿಯೋಗಗೊಳಿಸಲು ಸಲ್ಲಿಸಲ್ಪಟ್ಟ ಪ್ರತಿಯೊಂದೂ ವೈದ್ಯಲಿಖಿತವನ್ನು ಭೈಷಜ್ಯೀಯ ಪರಾಮರ್ಶೆಗೆ, ಒಳಪಡಿಸಲು ನೋಂದಾಯಿತ ಭೇಷಜಜ್ಞರು, ಉದ್ಯುಕ್ತರಾಗತಕ್ಕದ್ದು. ಈ ಕಾನೂನಿನ ಉದ್ದೇಶಗಳಿಗಾಗಿ, ಭೈಷಜ್ಯೀಯ ಪರಾಮರ್ಶೆಯನ್ನು ಈ ರೀತಿ ವ್ಯಾಖ್ಯಾನಿಸಲಾಗಿದೆ ಯಾವ ಒಂದು ಘಟ್ಟದಲ್ಲಿ ನೋಂದಾಯಿತ ಭೇಷಜಜ್ಞರು, ತಮ್ಮ ಜ್ಞಾನವನ್ನು ವೈದ್ಯರು ನಿರ್ದಿಷ್ಟಪಡಿಸಿದ ಔಷಧೋಪಚಾರಗಳ ಸುರಕ್ಷೆ, ಗುಣಮಟ್ಟ ಸಾಮರ್ಥ್ಯ ಮತ್ತು ಅವುಗಳ ಉಪಯೋಗದ ಪ್ರಬುದ್ಧತೆಯನ್ನು ಸಮರ್ಥಿಸುವಲ್ಲಿ ತೊಡಗಿಸಿಕೊಳ್ಳುವುದಾಗಿದೆ.

### 9. DUTIES OF REGISTERED PHARMACIST

# 9.1 Dispensing / Supply of Drugs:

- a) The various activities of dispensing (prescription assembly) like removal of drugs from the packing, filling the prescription etc. may be performed under the supervision of a registered pharmacist by any person who has been trained to perform these activities. However, the actual dispensing of drugs to patients shall only be performed by the Registered pharmacist after due verification of the prescription filled by others.
- A Registered pharmacist shall undertake a pharmaceutical assessment of every prescription presented for dispensing. For the purpose of the act, pharmaceutical assessment is defined as the point at which Registered pharmacist applies his knowledge to establish the safety, quality, efficacy and rational use of drugs treatments specified by a prescriber.







- (ಸಿ) ರೋಗಿಗಳ ಗೌಪ್ಯತೆಯನ್ನು ಎಲ್ಲಾ ಸಮಯಗಳಲ್ಲೂ ಕಾಪಾಡತಕ್ಕದ್ದು,
- (ಡಿ) ರೋಗಿಗಳಿಗಾಗಲೀ ಅಥವಾ ಆರೈಕೆದಾರತಿಗಾಗಲೀ ಸಮರ್ಪಕ ಮಾಹಿತಿ ಒದಗಿಸತಕ್ಕದ್ದು ಮತ್ತು ಎಲ್ಲೆಲ್ಲಿ ಕಾರ್ಯ ಸಾಧುವೋ ಅಲ್ಲಲ್ಲಿ ಈ ಮಾಹಿತಿ ಗ್ರಹಿಕೆಯನ್ನು ತಪಾಸಣೆ ಮಾಡತಕ್ಕದ್ದು.
- (ಇ) ಭೇಷಜೀಯಲ್ಲಿ ನಿರ್ವಹಿಸಲ್ಪಟ್ಟ ಎಲ್ಲಾ ವೈದ್ಯಲಿಖಿತಗಳಿಗೆ:
  - (i) ರೋಗಿಯ ವಿವರಗಳನ್ನು ತಪಾಸಣೆ ಮಾಡತಕ್ಕದ್ದು ಮತ್ತು ದೃಢೀಕರೀಸತಕ್ಕದ್ದು.
  - (ii) ಭೈಷಜ್ಯೀಯ ಪರಾಮರ್ಶೆ ನಡೆಸತಕ್ಕದ್ದು,
  - (iii) ಸೂಕ್ತ ದಾಖಲೀಕರಣ ನಿರ್ವಹಿಸತಕ್ಕದ್ದು.
- (ಎಫ್) ವೈದ್ಯಲಿಖಿತಗಳ ಪರಾಮರ್ಶೆಯು, ಈ ಕೆಳಗಿನ ವಿಮರ್ಶೆಗಳನ್ನು ಒಳಗೊಂಡಿರತಕ್ಕದ್ದಾದರೂ, ಕೇವಲ ಅವುಗಳಿಗೆ ಮಾತ್ರ ಸೀಮಿತವಾಗತಕ್ಕದ್ದಲ್ಲ.
  - (i) ಆ ವೈದ್ಯಲಿಖಿತವು ಕಾನೂನುಗಳಲ್ಲಿ ಮಾನ್ಯವಾಗಿದೆಯೇ?
  - (ii) ಆ ವೈದ್ಯಲಿಖಿತದಲ್ಲಿ ಔಷಧಿಯ ಒಂದು ಸೇವಿಸುವ ಸೂಕ್ತ ನಮೂನೆ ಮತ್ತು ಸೇವನೆಯ ಸೂಕ್ತ ಮಾರ್ಗದ ವಿವರ ಸೇರಿಸಲ್ಪಟ್ಟಿದೆಯೇ?
  - (iii) ರೋಗಿಯ ಪರಿಸ್ಥಿತಿಗೆ ವೈದ್ಯಲಿಖಿತವು ಸೂಕ್ತವಾಗಿದೆಯೇ? ಇಲ್ಲವೇ?
  - (iv) ಚಿಕಿತ್ಸಾ ಅವಧಿ ಸರಿಯಾಗಿದೆಯೇ?
  - (v) ರೋಗಿಯ ಮಾನದಂಡಗಳಿಗೆ (ವಯಸ್ಸು, ತೂಕ ಇತ್ಯಾದಿ) ಮತ್ತು ಈ ಹಿಂದಿನ ಔಷಧೋಪಚಾರಗಳಿಗೆ ಅನುಗುಣವಾಗಿಯೇ ವೈದ್ಯಲಿಖಿತ ಇದೆಯೇ?
  - (vi) ಸೇವಿಸುತ್ತಿರುವ ಇತರ ಔಷಧಗಳೊಂದಿಗೆ ವೈದ್ಯಲಿಖಿತವು ಹೊಂದಾಣಿಕೆ ಇದೆಯೇ?
  - (vii) ಸೂತ್ರ ಸಂಹಿತೆ, ಮತ್ತು ಮಾರ್ಗದರ್ಶಕ ಸೂಚನೆಗಳು ಯಾವುದಾದರೂ ಇದ್ದರೆ, ವೈದ್ಯಲಿಖಿತವು ಅವುಗಳಿಗೆ ಸುಸಂಗತವಾಗಿದೆಯೇ?
  - (viii) ಅಡ್ಡ ಪರಿಣಾಮಗಳು ಮತ್ತು ಪ್ರತಿಕೂಲ ಔಷಧಿ ಪ್ರತಿಕ್ರಿಯೆಗಳು ತಲೆದೋರುವ ಸಾಧ್ಯತೆ ಇದೆಯೇ?
  - (ix) ವ್ಯತಿರಿಕ್ಕವಾಗಿ ಸೂಚಿತವಾಗಿದೆಯೇ?
  - (x) ವೈದ್ಯಲಿಖಿತದ ಔಷಧಿಗಳು, ರೋಗಿಯಿಂದ ದುರ್ಬಳಕೆ ಮತ್ತು ಸೂಕ್ತವಲ್ಲದ ಬಳಕೆಗೆ ಉಪಯೋಗಿಸಲ್ಪಡುವ ಸುಪ್ತ ಸಾಮರ್ಥ್ಯಹೊಂದಿವೆಯೇ?
  - (xi) ವೈದ್ಯಲಿಖಿತವು, ಧಾರಕದಲ್ಲಿ ಸೇರಿಸಬೇಕಾದ ಬೇಡಿಕೆಗಳನ್ನು ಪೂರಕವಾಗಿ ಒಳಗೊಂಡಿದೆಯೇ?
- (ಜಿ) ಬೇಕಾಗಿರುವ ಔಷಧಿ ಉತ್ಪನ್ನಗಳ ಸಂಯುಕ್ತಗೊಳಿಸುವಿಕೆ, ವಿನಿಯೋಗಗೊಳಿಸುವೆಕೆ ಮತ್ತು ಧಾರಕ ಅಂಟಿಸುವಿಕೆ ಈ ಕೆಳಗಿನವನವನ್ನು ಖಚಿತ ಪಡಿಸುವಂತಿರತಕ್ಕದ್ದು
  - (i) ಔಷಧ ಉತ್ಪನ್ನವು ವೈದ್ಯಲಿಖಿತಕ್ಕೆ ಸಮನಾಗಿ ಸರಿ ಹೊಂದಬೇಕು.
  - (ii) ಔಷಧ ಉತ್ಪನ್ನವು ಗಡುವಿನ ತಾರೀಖು ಮೀರಿರಬಾರದು.
  - (iii) ಔಷಧ ಉತ್ಪನ್ನವು ಸೂಕ್ತ ರೀತಿಯಲ್ಲಿ ಸಂಯುಕ್ತಗೊಳಿಸಲ್ಪಟ್ಟಿದ್ದು (ಅಗತ್ಯವಾದಲ್ಲಿ) ಪೊಟ್ಟಣಗೊಳಿಸಿದ್ದು ಮತ್ತು ಧಾರಕ ಅಂಟಿಸಲ್ಪಟ್ಟಿರತಕ್ಕದ್ದು.
  - (iv) ವಿನಿಯೋಗಗೊಳಿಸಿದ ನಿಖಿರತೆಯನ್ನು ನೋಂದಾಯಿತ ಭೇಷಜಜ್ಞರು ತಾಳೆ ನೋಡತಕ್ಕದ್ದು.
  - (v) ಯೋಗ್ಯ ರೀತಿಯಲ್ಲಿ ದಾಖಲಾತಿಗಳನ್ನು ತಯಾತಿಸಿಡತಕ್ಕದ್ದು.
- (ಎಚ್) ರೋಗಿಗೆ / ಆರೈಕೆದಾರನಿಗೆ ಔಷಧ ಉತ್ಪನ್ನವನ್ನು ಹಸ್ತಾಂತರಿಸುವ ಕ್ರಿಯೆಯು, ಈ ಕೆಳಗಿನವನ್ನು ಖಾತ್ರಿಪಡಿಸುವ ರೀತಿಯಲ್ಲಿರತಕ್ಷದ್ದು.
  - (i) ರೋಗಿಗೆ / ಆರೈಕೆದಾರನಿಗೆ, ನೋಂದಾಯಿತ ಭೇಷಜಜ್ಞರೇ ಔಷಧ ಉತ್ಪನ್ನವನ್ನು ಹಸ್ತಾಂತರಿಸತಕ್ಕದ್ದು.
  - (ii) ಔಷಧಗಳ ಮೇಲೆ ಸೂಕ್ತ ಮಾಹಿತಿಯನ್ನು ರೋಗಿಗೆ / ಆರೈಕೆದಾರನಿಗೆ ಒದಗಿಸತಕ್ಕದ್ದು.

- Patient confidentiality shall be maintained at all times.
- d) Appropriate information shall be provided to the patient or the care giver and, where possible, understanding of this information should be checked.
- e) For all prescriptions handled by the pharmacy:
  - i) Patient details shall be checked and confirmed
  - ii) Pharmaceutical assessment shall be made
  - iii) Proper documentation shall be maintained.
- f) Assessment of the prescription should include but not be limited to assessment of whether:
  - i) The prescription is legally valid.
  - ii) The prescription includes an appropriate dosage form and appropriate route of administration.
  - iii) Prescription is appropriate to the patient's condition.
  - iv) Duration of treatment is correct.
  - Prescription is appropriate according to patient's parameters (age, weight etc.) and previous medication.
  - vi) Prescription is compatible with other medications.
  - vii) Prescription is consistent with formulary and guidelines, if any.
  - viii) Possibility of side effects and ad-verse drug reactions exist
  - ix) Contra-indicated.
  - x) Potential for misuse and inappropriate use of the medicines in prescription by patient exists.
  - xi) Prescription is complying with labeling requirements.
- g) Compounding, dispensing and labeling of required drug products should ensure that
  - i) The drug product matches the prescription.
  - ii) The drug product has not expired.
  - iii) The drug product is appropriately compounded (if necessary), packed and labeled appropriately.
  - iv) The accuracy of dispensing is checked by Registered Pharmacist.
  - v) Proper documentation is made.
- h) Delivery of the drug product to the patient/carer is done in such a way as to ensure that:
  - The Registered pharmacist hands over the drug to the patient/carer.
  - Appropriate information on drugs is provided to the patient/carer.







# 9.2 ಔಷಧದ ತರ್ಕಸಮ್ಮತ ಉಪಯೋಗದ ಪ್ರೋತ್ಸಾಹಕ್ಕಾಗಿ ಭೇಷಜಜ್ಜ:

ಔಷಧಗಳ ತರ್ಕಸಮ್ಮತ ಉಪಯೋಗವನ್ನು ಪ್ರೋತ್ಸಾಹಿಸಲು, ಭೇಷಜಜ್ಞರು, ಈ ಕೆಳಗಿನಂತಹ ಚಟುವಟಿಕೆಗಳಲ್ಲಿ ತನ್ನನ್ನು ತೊಡಗಿಸಿಕೊಳ್ಳತಕ್ಷದ್ದು.

- (i) ಆಸ್ಪತ್ರೆ ಮಟ್ಟದಲ್ಲಿ ಮತ್ತು ರಾಜ್ಯ / ರಾಷ್ಟ್ರ ಮಟ್ಟಗಳಲ್ಲಿ ಎರಡೂ ಕಡೆ, ಸೂತ್ರ ಸಂಹಿತೆಗಳನ್ನು ತಯಾರಿಸುವುದು.
- (ii) ಔಷಧ ತಯಾರಿಕಾ ಸಂಸ್ಥೆಗಳಿಂದ ತಯಾರಿಸಲ್ಪಟ್ಟ ಮಾರಾಟ ಪ್ರೋತ್ಸಾಹಿಸುವ ವಸ್ತುಗಳ ತೀಕ್ಷ್ಣ ಮೌಲ್ಯ ಮಾಪನ ಮಾಡತಕ್ತದ್ದು.
- (iii) ಮೌಲ್ಯಮಾಪನದ ಮಾಹಿತಿಗಳನ್ನು ಅಧಿಕೃತ ಮೂಲಗಳ ಮುಖಾಂತರ ಪ್ರಸರಣಗೊಳಿಸುವುದು.
- (iv) ಮುಂದುವರಿಸುವ ಕಲಿಕಾ ಕಾರ್ಯಕ್ರಮಗಳ ಮುಖಾಂತರ ಔಷಧಗಳ ಬಗೆಗಿನ ಜ್ಞಾನವನ್ನು ಇಂದಿನ ತನಕ ಅನ್ವಯವಾಗುವಂತೆ ವಿಸ್ತಾರ ಮಡತಕ್ಕದ್ದು ಮತ್ತು ಆರೋಗ್ಯ ವೃತ್ತಿಪರರಿಗೆ ಕಲಿಕಾ ಕಾರ್ಯಕ್ರಮಗಳನ್ನು ಆಯೋಜಿಸತಕ್ಕದ್ದು.
- (v) ರೋಗಿಗಳಿಗೆ ಮಾಹಿತಿ ನೀಡುವ ಕರಪತ್ರಗಳನ್ನು ತಯಾರಿಸುವುದು ಮತ್ತು ಪ್ರಸಾರಗೊಳಿಸುವುದು.

### 9.2 Pharmacist for promotion of rational drug use:

To promote rational use of drugs, the pharmacist shall involve himself in activities such as:

- Preparation of formularies both at the hospital level and at state/ national levels.
- ii) Critical assessment of promotional materials prepared by the drug companies.
- iii) Dissemination of evaluated information through authorized sources.
- iv) Updating the knowledge of drugs through continuing education programmes and also to organize educational programmes for health professionals.
- Preparation and dissemination of patient information leaflets.

# **KSPC News**



# 1. Rajiv Memorial Education Society's College (RMES) of Pharmacy, Kalburgi

Rajiv Memorial Education Society's College (RMES) of Pharmacy, Kalaburgi in association with Karnataka State Pharmacy Council, Bengaluru celebrated 'World Pharmacists Day' on 25<sup>th</sup> September 2021 to pay tributes to pharmacists for the role they play in improving global health and to encourage the activities that advocate the role of the pharmacist in improving health in every corner of the world.

To ensure better recognition of the Pharmacist and Pharmacy profession in society, Karnataka State Pharmacy Council (KSPC) has distributed Apron, Nameplate and Key Chain for the Licensed Renewed Registered Pharmacists who are working in retail or hospital Pharmacy and Academician in Colleges across Kalaburgi district.

Also, 5 senior Pharmacists and 6 pharmacists covid warriers have been felicitated during this occasion.





Dr. Ashok Kumar Malpani, Principal, RMES College of Pharmacy has delivered a talk on this year WPD theme: Pharmacy - 'Always trusted for your Health'.

The esteemed guests who attended this celebration were Sri. Dattatreya Patil Revoor, MLA Kalaburagi South, Sri. Amaresh Tumbagi, Additional Drugs Controller, Karnataka, Sri. Nagaraj, Deputy Drug Controller, Kalaburagi, Sri. D. A. Gundu Rao, Vice President, KSPC, Sri.Y. Veeranarayana Gowda, EC Member, KSPC.

Dr. Kishore Singh Chatrapathi, President, Rajiv Memorial Education Society and Executive Committee Member, KSPC, Sri Suraj Prasad Tiwari, Vice President, RME Society, Sri Umesh Shetty, Secretary, RME Society and Governing council members Prof Hariprasanna R C, Prof Siddanna Durgad, Prof Vishwanath Jeevangi, Sri Baswaraj Ranjolkar were present on this occasion.







# 2. KRE Trust's Rani Chennamma College of Pharmacy, Belagavi

KRE Trust's Rani Chennamma College of Pharmacy and RML College of Pharmacy in collaboration with Karnataka State Pharmacy Council (KSPC), Belagavi District Retail Pharmacy Association and Belagavi City Chemist and Druggist Association organised World Pharmacists Day celebration at Rani Chennamma College of Pharmacy (RCCP), Belagavi on 25th September 2021 to create awareness about the role of pharmacist in improving health. The theme for this year was "Pharmacy: Always trusted for your health".



During this event aprons, name badges and key chains were distributed to the registered pharmacists in the Belagavi District.

The dignitaries for the programme were Shri Gangadhar V. Yavagal, President KSPC, Shri R. S. Madarkhandi, KSPC member and Chairman and CEO of RCCP, Belagavi, Shri Jayant Salunke, President Belagavi District Retail Pharmacy Association, Shri Shyamgouda Patil, President, Belagavi City Chemist and Druggist Association, Dr. A. D. Taranalli, Director of RCCP, Belagavi, Dr. Vijayanand Pujari, Principal RCCP, Belagavi, Shri N. G. Kulkarni, Shri S. D. Sadalgi, Belagavi City Chemist and Druggist Association took active participation in the programme.



Shri Gangadhar V. Yavagal, President, KSPC highlighted about the various activities of KSPC and unique programme of distributing aprons to the registered pharmacists.

Shri R. S. Madarkhandi, KSPC member and Chairman of RCCP who enlightened the audience with his motivational talk.



Shri R. S. Madarkhandi and Shri Gangadhar V Yavagal handed over the aprons, name badges and key chains as a symbol of respect to few of the eminent pharmacists on the stage. Later the faculty of RCCP, Belagavi distributed the same to all the registered pharmacists present. The programme was concluded with a vote of thanks by Mrs. Rashmi Surve, Asst. Professor, RCCP, Belagavi.



This program has proved to establish the stand of the pharmacist amidst other healthcare professionals and also served as an encouraging boost to emerging young pharmacists at Belagavi District.

# **Renewal of Registration - 2022**

The Renewal of Registration for the year 2022 will be opened from 1st December 2021. The Registered Pharmacist can avail this service through our website and mobile app. Renew your registration without fail before the grace period 31-03-2022. For any queries, mail your registration number, registered mobile number and email id to kspcreg@gmail.com.

Visit: www.kspcdic.com

Registrar

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# Karnataka Pharmacy Council Registered Pharmacist Welfare Trust (KPCRPWT)

**Karnataka State Pharmacy Council** started a social welfare scheme for the benefit of the family of the registered pharmacist with a concern on the welfare of the pharmacist and his/her family in the year 1998 by a name **Karnataka Pharmacy Council Registered Pharmacist Welfare Trust (KPCRPWT).** 

This is a unique scheme established for the first time in India with a concern on the welfare of the pharmacist and his/her family. Till date many families have been benefited by the scheme.

The scheme is extended to the ailing pharmacists suffering from diseases such as Cancer, Kidney Failure, Bypass Surgery and other ailments of serious nature (in case the scheme is well responded by the members) as decided by the trust.

Registered Pharmacist who has not enrolled to this scheme and whose Registration validity is current and age <60 years can login to <a href="https://www.kspcdic.com">www.kspcdic.com</a> and enroll for the same to avail the benefit.

For more information regarding the scheme, you can visit <a href="https://kspcdic.com/krpwt">https://kspcdic.com/krpwt</a>

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