PHARMACOALERT

News Letter

Drug Safety Alert, New Drug Marketed, Drug Interactions and Banned Drugs

Published Monthly by the Department of Pharmacology, Dr.RMLIMS

Second Issue December 2019

The department of Pharmacology, Dr.RMLIMS, Lucknow, presents the second issue of its newsletter **PHARMACOALERT**. As our institute is an ADR Monitoring Centre (AMC) under PvPI, in this issue we are putting forth the information regarding ADR reporting along with the ADR form, with the aim to reinforce the reporting culture among health care professionals. Apart from the regular information like drug alerts, marketed new drugs and interesting facts from the history, we will also continue with the information pertaining to medication errors in this and subsequent issues. We are also presenting the glimpses of the **CME cum Sensitization Program on Pharmacovigilance and Rational Therapeutics,** organized on 15th November, 2019 by our Department in collaboration with the NCC, PvPI, IPC (MoHFW), Govt of India.

-Dr Atul Jain

Reporting Adverse Drug Reactions at our AMC (DR.RMLIMS)

What to report ?

Report serious adverse drug reactions. A reaction is serious when the patient outcome is:

- Death
- Life-threatening
- Hospitalization (initial or prolonged)
- Disability (significant, persistent or permanent)
- Congenital anomaly
- Required intervention to prevent permanent impairment or damage

Report non-serious, known or unknown, frequent or rare adverse drug reactions due to Medicines, Vaccines and Herbal products.

Who can report ?

- All healthcare professionals (Clinicians, Dentists, Pharmacists and Nurses) can report adverse drug reactions

Where to report ?

- Duly filled Suspected ADR Reporting Form can be send to the *Pharmacovigilance associate* of our AMC, *Mr. Saket Verma* or directly to the National Coordination Centre (NCC).
- Call 9044280875 (*Mr. Saket Verma)* or mail to saketverma06188@gmail.com
- Call on Helpline (Toll Free) 1800 180 3024 to report ADRs.
- Or can directly mail this filled form to pvpi@ipcindia.net or pvpi.ipcindia@gmail.com

***Mandatory field for suspected ADR reporting form (downloadable from……**
https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf.documents/Consumer_Section_PDFs/ADRRF_2.pdf

- Patient initials, age at onset of reaction, reaction term(s), date of onset of reaction, suspected medication(s) and reporter information.

Version-1.2

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For VOLUNTARY reporting of Adverse Drug Reactions by Healthcare Professionals

INDIAN PHARMACOPOEIA COMMISSION
(National Coordination Centre-Pharmacovigilance Programme of India)
Ministry of Health & Family Welfare, Government of India
Sector-23, Raj Nagar, Ghaziabad-201002

FOR AMC/NCC USE ONLY

AMC Report No. :

Report Type □ Initial □ Follow up

Worldwide Unique No. :

A. PATIENT INFORMATION

1. Patient Initials _____

2. Age at time of Event or Date of Birth _____

3. M □ F □ Other □

4. Weight _____ Kgs

12. Relevant tests/ laboratory data with dates

B. SUSPECTED ADVERSE REACTION

5. Date of reaction started (dd/mm/yyyy)

6. Date of recovery (dd/mm/yyyy)

7. Describe reaction or problem

13. Relevant medical/ medication history (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/renal dysfunction etc.)

14. Seriousness of the reaction: No □ if Yes □ (please tick anyone)

□ Death (dd/mm/yyyy) □ Congenital-anomaly
□ Life threatening □ Required intervention to Prevent permanent
□ Hospitalization/Prolonged impairment/damage
□ Disability □ Other (specify)

15. Outcomes

□ Recovered □ Recovering □ Not recovered
□ Fatal □ Recovered with sequelae □ Unknown

C. SUSPECTED MEDICATION(S)

S.No	8. Name (Brand/Generic)	Manufacturer (if known)	Batch No. / Lot No.	Exp. Date (if known)	Dose used	Route used	Frequency (OD, BD etc.)	Therapy dates		Indication	Causality Assessment
								Date started	Date stopped		
i											
ii											
iii											
iv											

S.No as per C	9. Action Taken (please tick)						10. Reaction reappeared after reintroduction (please tick)			
	Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown	Yes	No	Effect unknown	Dose (if reintroduced)
i										
ii										
iii										
iv										

11. Concomitant medical product including self-medication and herbal remedies with therapy dates (Exclude those used to treat reaction)

S.No	Name (Brand/Generic)	Dose used	Route used	Frequency (OD, BD, etc.)	Therapy dates		Indication
					Date started	Date stopped	
i							
ii							
iii							

Additional Information:

D. REPORTER DETAILS

16. Name and Professional Address: _____

_____

Pin: _____ E-mail _____

Tel. No. (with STD code) _____

Occupation: _____ Signature: _____

17. Date of this report (dd/mm/yyyy):

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. Programme staff is not expected to and will not disclose the reporter's identity in response to a request from the public. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction.

Drug Alert:

In view of the recent news of presence of **N-nitrosodimethylamine (NDMA)** impurity in **Ranitidine,** FDA testing have found much lower level of NDMA than the levels some third-party scientists first claimed, although some levels still exceed what the FDA considers acceptable for these medicines. US-FDA, has asked manufacturers of Ranitidine and Nizatidine products to expand their testing for NDMA medication before making them available to consumers. If testing shows NDMA level above the acceptable daily intake limit of **96 nanograms per day or 0.32 parts per million** for Ranitidine, the manufacturer must inform the agency and should not release the lot for consumer use. There is some evidence which suggest that there may be formation of NDMA in the body after taking Ranitidine or Nizatidine, if there is presence of nitrites in the body. So patients who wish to continue taking these drugs should consider limiting their intake of nitrite-containing foods, e.g. processed meats and preservatives like sodium nitrite.

Medication errors:

Medication errors can occur in any steps during the process of medication use. It can be broadly classified into three types:

1. Prescribing errors 2. Dispensing errors 3. Administering errors

Prescription errors account for a significant proportion (70%) of medication errors. Using *Delphi technique*, Dean and collegue adopted the definition of prescription error as "a clinically meaningful prescribing error occurs when, as a result of a prescribing decision or prescription writing process, there is an unintentional significant reduction in the probability of treatment being timely and effective or and increased risk of harm when compared to generally accepted practice." Prescription errors occurs when:

- Physician writes a prescription without considering the patient's clinical status, age, body weight, comorbidity, status of allergy, concomitant medications, etc.
- Writing an unclear prescription
- Unnecessary continuation of a prescription for prolong duration
- Continuation of a drug in presence of a clinically significant ADR or Drug interaction
- Incomprehensible writing
- Using abbreviations
- Not mentioning proper direction of use
- Not writing prescription in full if a change has been made to it

Dispensing error mostly oocurs during transcribing and verifying the medication mostly by pharmacists and nurses. It mainly occurs due supply of wrong medicine, or wrong strength of the prescribed medicine, or wrong quantity of medicine, or wrong direction for use or wrong drug dosage calculation.

Administration errors is having a incidence rate of around 30%. Studies have reported that 26% of all preventable ADRs occur during this stage. As we are aware that nurses are mostly responsible for administering the medication during hospital stay and the patient or any family member or caregivers are responsible for medication administration for ambulatory patients, thus being responsible for this type of error. Example of this type of error may be administration of wrong medicine, by wrong route, or wrong dose, to the wrong patient, or omission of a dose.

From the past-Important events in December:

December 3, 1984: A deadly gas leak (methyl isocyanate) at a Union Carbide plant in Bhopal, India, killed at least 3,000 persons and injured more than 200,000.

December 10, 1896: Swedish chemist Alfred Nobel died at San Remo, Italy. His will stipulated that income from his $9 million estate be used for awards recognizing persons making valuable contributions to humanity.

December 21, 1846: Anaesthesia was used for the first time in Britain during an operation at University College Hospital in London, performed by Robert Liston who amputated the leg of a servant.

December 25, 1821, Birthday: American nurse and philanthropist Clara Barton founder of American Red Cross.

December 27, 1822, Birthday: French chemist-bacteriologist Louis Pasteur.

FDA approves novel treatment to target abnormality in sickle cell disease:

Recently U.S. FDA has granted accelerated approval to **Voxelotor** for the treatment of sickle cell disease (SCD) in adults and pediatric patients 12 years of age and older. This approval provides additional hope to the 100,000 people in the U.S., and more than 20 million globally, who live with this debilitating blood disorder. **Voxelotor** is an **inhibitor of deoxygenated sickle hemoglobin polymerization**, which is the central abnormality in sickle cell disease. It has disease modifying potential and reduce the binding of the sickle cells to each other, thereby increasing haemoglobin levels and decreasing hemolysis in sicke cell disease patients. This therapy provides a new treatment option for patients with this serious and life-threatening condition."Common side effects for patients taking **Voxelotor** are headache, diarrhea, abdominal pain, nausea, fatigue, rash and pyrexia (fever). It has also received Orphan Drug designation.

FDA approves new treatment for adults with partial-onset seizures:

US FDA has given approval to **Cenobamate** tablets to treat partial-onset seizures in adults.

The recommended maintenance dose of Cenobamate is 200 mg/day, upto a maximum of 400 mg/day, based on their clinical response and tolerability. It is a **selective blocker of the inactivated state of voltage-gated sodium channel (VGSCs)**. In addition to it, Cenobamate also enhances presynaptic release of γ-aminobutyric acid (GABA), thereby increasing inhibitory GABAergic neurotransmission. Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) and QT shortening with ventricular fibrillation, increase the risk of suicidal thoughts or behavior in patients, somnolence, fatigue, dizziness, trouble with walking and coordination, and diplopia are associated adverse reactions with the use of Cenobamate.

New drugs approved In November 2019, (DCGI):

Sl No.	Name of the Drug	Indication
1	**Abemaciclib** 50mg, 100mg, 150mg and 200mg film coated tablets	(i) Abemaciclib is indicated for the treatment of women with hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2) negative locally advanced or metastatic breast cancer in combination with an aromatase inhibitor or fulvestrant as initial endocrine-based therapy, or in women who have received prior endocrine therapy.• In pre-or perimenopausal women, the endocrine therapy should be combined with a luteinising hormone-releasing hormone (LHRH) agonist. (ii) As monotherapy for the treatment of adult patients with HR-positive, HER2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting.
2	**Ripasudil** hydrochloride hydrate bulk drug and Ripasudil Eye drops 0.4% w/v	To treat glaucoma and ocular hypertension when other medicines for glaucoma have insufficient effect or cannot be used.
3	**Diperoxochloric acid** concentrate and Diperoxochloric acid topical solution	Indicated for wound healing in diabetic neuropathic ulcers of skin and subcutaneous tissues reduction.

A CME cum sensitization programme on "Pharmacovigilance & rational therapeutics" was organised by department of Pharmacology under the guidance of Dr. Atul Jain, Professor & Head, Department of Pharmacology and Coordinator AMC, at Dr. RMLIMS, on 15th November, 2019. Total of 297 participants attended the CME including doctors from various Medical Colleges in Luckow. Dr. R.K Dixit, Professor, Dept of Pharmacology KGMU, Lucknow, delivered the Guest Lecture on **"Role of Pharmacovigilance in Rational Pharmacotherapeutics: A key for best Therapeutic Outcomes"**. A ***'Poster Competition'*** was also organised for MBBS & Nursing students on "Pharmacovigilance and reporting of Adverse Drug Reactions". On this occasion, the monthly newsletter by the Department of Pharmacology "**PHARMACOALERT**" was released by Director, Dr. RMLIMS, Prof. A.K Tripathi.

Glimpses from CME

Feedback and Suggestions may be sent to Department of Pharmacology, Dr.RMLIMS, Lucknow at email id: pharmacologyrmlims@gmail.com