



PHARMACOALERT



News Letter

About Drug Safety Alert, New Drug Marketed, Drug-Drug Interactions and List Of Banned Drugs

Published Monthly by the Department of Pharmacology, Dr.RMLIMS

First Issue

November 2019

Patron:

Dr. A K Tripathi,
Director, Dr. RMLIMS

The department of Pharmacology, Dr.RMLIMS, Lucknow, presents the first issue of its newsletter **PHARMACOALERT**. The purpose of the newsletter is to bring forth the relevant and important information from the ever-changing and evolving world of medicines.

Editorial Team:**Chief Editor:**

Dr. Atul Jain

With this issue, the new information pertaining to drug safety alert, new drugs, etc. shall be shared periodically with the sole intention to contribute in improving patient care. A section has been dedicated to enjoyable historical account which shall encourage relaxed learning.

Editor:

Dr Arpita Singh

Hope you all will enjoy reading this issue and with subsequent issues you shall become partners in our learning curve.

Co-editors:

Dr Pooja Shukla ,
Dr Joonmoni Lahon

-Dr Atul Jain

DEPARTMENT OF PHARMACOLOGY**DR.RMLIMS, LUCKNOW****MISSION STATEMENT**

To impart conceptual teaching and training of pharmacology and therapeutics with innovative and Evidence based methodology to Indian Medical Graduate who shall be the future forebears for prescribing rationally with patient centred approach.

To facilitate and encourage collaboration across various disciplines for conducting ethical research and applying remarkable scientific innovations for health gain of the society.

ADR Monitoring Centre
Department of Pharmacology, Dr.RMLIMS, Lucknow
under Pharmacovigilance Program of India (PvPI)

The Pharmacovigilance Program of India (PvPI) was started in July 2010 by Ministry of Health and Family Welfare, Govt. of India with the vision to improve patient safety and welfare in the Indian Population by monitoring drug safety and thereby reducing the risk associated with use of medicines.

The AIIMS, New Delhi was established as the National Coordination Centre (NCC) for PvPI, which in 2011 was shifted to Indian Pharmacopoeia Commission (IPC), Ghaziabad. Since then, the PvPI has collaborated with several national health programmes and research institutions.

To monitor Adverse Drug Reactions (ADRs), ADR Monitoring Centre (AMC), have been set up all over India, which send reports to NCC. NCC-PvPI was started with 22 AMCs in the initial phase and currently has 250 AMCs which include various medical colleges.

Our Institute, Dr.RMLIMS, Lucknow is one such AMC under this PvPI. Dr Atul Jain, Professor & Head, Department of Pharmacology is the coordinator of our AMC.

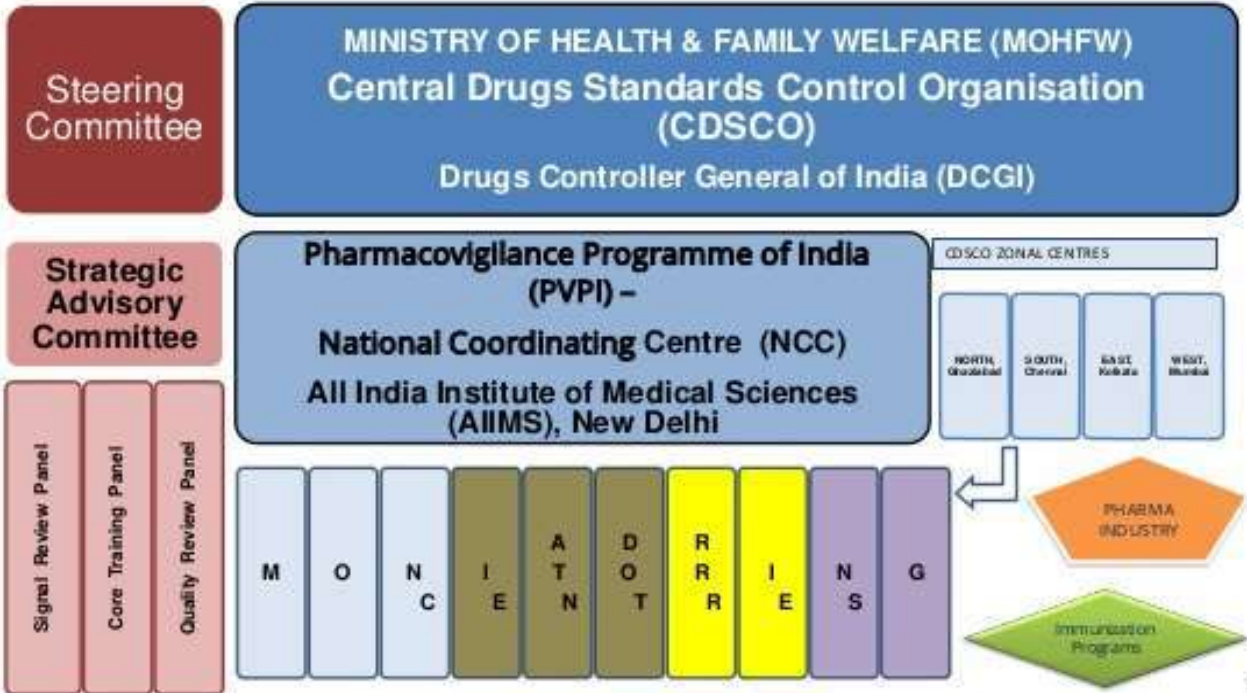
The NCC-PvPI collects, collates and evaluates spontaneous ADR reports from the AMCs which are reported by health care professionals (HCP) and consumers/ patients.

WHO on 30th October, 2017 recognized IPC-PvPI as a WHO-Collaborating Centre for Pharmacovigilance in public health programmes and regulatory services.

Communicating safety information to patients and HCPs is a public health responsibility borne by PvPI. Till date, several specific drug safety alerts/ signals have been identified and communicated to the HCP and regulatory authority – CDSCO, for taking appropriate regulatory actions.

*At our AMC, ADRs can be reported to the **Pharmacovigilance associate, Mr. Saket Verma**, who is appointed in the Department of Pharmacology by IPC, Ghaziabad, under PvPI.*

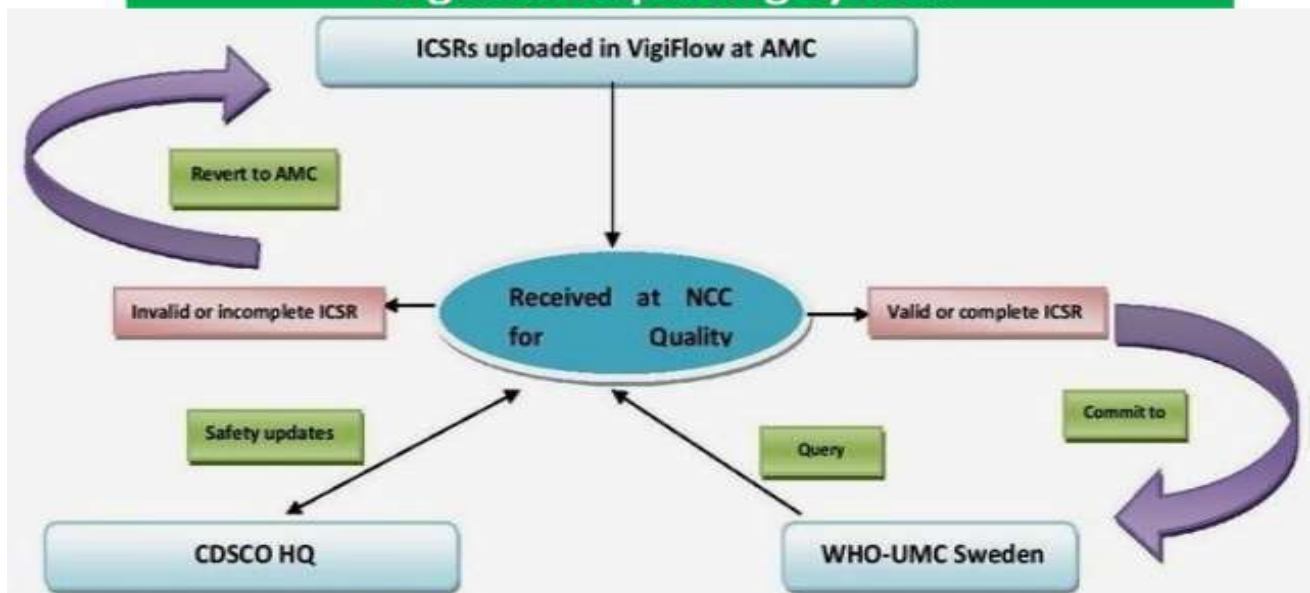
GOVERNANCE STRUCTURE - PVPI



ADR Reporting from our AMC through Vigiflow:

Vigiflow is a web based individual case safety report (ICSR) management system that is specially designed for used by National Centre in the WHO Program for International Drug Monitoring.

Vigiflow Reporting System



Drug Alert:

US-FDA has issued a global alert to patients and health care professionals over the possible presence of **N-nitrosodimethylamine (NDMA)** in many brands of **Ranitidine**. The N-nitrosodimethylamine (NDMA) has been classified by International Agency for Research on Cancer (IARC) as probably carcinogenic to humans. There are over 180 generic versions of Ranitidine in the market. GSK the global leader in sales of Ranitidine has stopped sales following the US-FDA. The NDMA levels FDA found are similar to the levels a consumer would expect to be exposed to when eating common foods like grilled and smoked meats. Drugs Controller General of India (DCGI) directed that the pharmaceutical companies to submit data on these drugs and state/UT drug regulatory authorities to assess the levels of this impurity (NDMA) in various marketed preparations of Ranitidine and take necessary measures to ensure patient safety.

Medication errors

Drug therapy is necessary and important aspect for management of diseases and there has been an increase in medication use by health services throughout the world. But this substantial and increasing medication use and medication management process give rise to a frequently encountered serious problem, that is **medication error**. The United States National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) defines a medication error as: “any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing, order communication, product labelling, packaging, and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use.” (NCC MERP, 1995)

Medication errors can occur at any stage during the process of medication use, which may be the result of errors in the act of writing (**prescription errors**), dispensing, administering, consumption and monitoring, etc. Irrational prescribing, inappropriate prescribing, underprescribing, overprescribing, and ineffective prescribing, arising from erroneous medical judgement or decision concerning treatment also account for medication errors. The Institute of Medicine (IOM), USA report also estimated that more than 70,000 lives are lost per year as a result of medication errors. It has been estimated that in some countries approximately 6-7% of hospital admissions appear to be medication related, with over two-thirds of these considered avoidable and thus, potentially due to medication errors. Moreover, they increase the overall health care expenditures, costs between \$17 billion and \$29 billion per year in hospitals nationwide. These medication errors are harmful not only to the patients, but also affect their caregivers and the healthcare system. Therefore, we should understand the seriousness of this problem and find out measures to address this issue, which will focus on enhanced patient safety with safe use of medication.

New breakthrough therapy for cystic fibrosis:

The U.S. FDA (Food and Drug Administration) approved Trikafta (**Ellexacaftor/Ivacaftor/Tezacaftor**), the first triple combination therapy available to treat patients 12 years and older with **cystic fibrosis** who have at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene, which is estimated to represent 90% of the cystic fibrosis population. This three drugs combination **target the defective CFTR protein** and helps the protein made by the CFTR gene mutation function more effectively.

Rash and influenza (flu) events were serious adverse drug events (SAE) that occurred more frequently in patients receiving this combination drug. The most common adverse drug reactions included headaches, upper respiratory tract infections, abdominal pains, diarrhea, rashes, increased liver enzymes (ALP and AST), nasal congestion, increased blood creatine phosphokinase, influenza, sinusitis and increased serum bilirubin. It should be used with caution in patient on drugs or food that are inducers or inhibitors of CYP3A.

New drugs approved In October 2019 (DCGI):

Name of the Drug	Indication
Acalabrutinib 100mg capsules	For the treatment of patients with Mantle Cell Lymphoma (MCL) who have received atleast one prior therapy

From the past-Important events in November:

November 1, 1848 - The first medical school for women opened in Boston. The Boston Female Medical School was founded by Samuel Gregory with just twelve students. In 1874, the school merged with the Boston University School of Medicine, becoming one of the first co-ed medical schools.

November 3, 1839 - The first Opium War between China and Britain began after British frigates blew up several Chinese junks.

November 8, 1895 - X-rays (electromagnetic rays) were discovered by Wilhelm Roentgen at the University of Wuerzburg in Germany.

November 14, 1666 - The first experimental blood transfusion took place in Britain, utilizing two dogs.

November 20, 1945 - The Nuremberg War Crime Trials began in which 24 former leaders of Nazi Germany were charged with conspiracy to wage wars of aggression, crimes against peace, war crimes, and crimes against humanity. These trials form the base for ethical codes popularly known as "**Nuremberg Code**", which came into effect in 1947.

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