DEPARTMENT OF PHARMACOLOGY
ARMED FORCES MEDICAL COLLEGE, PUNE-40

Drug Safety Bulletin: Be Aware

Issue: Second; Oct-Dec 2021

Dear Readers,
The purpose of this bulletin is to disseminate important safety information related to drugs and medical devices from drug regulatory agencies like CDSCO, US FDA, European Union. This will help clinician to be aware of latest safety issues with drugs. The current issue highlights recent safety updates on JAK inhibitors, Statins, Methotrexate and alerts from PvPI database. Feedback and suggestions, if any, may be sent at email Id: pvpiafmc@gmail.com.

Increased risk of serious heart-related events, cancer, blood clots, and death for JAK inhibitors[1]

Based on a completed U.S. Food and Drug Administration (FDA) review of a large randomized safety clinical trial, it is concluded that there is an increased risk of serious heart-related events such as heart attack or stroke, cancer, blood clots, and death with Janus kinase (JAK) inhibitors like tofacitinib, baricitinib and upadacitinib.

What is US-FDA doing?:

Changes will be made to several sections of the prescribing information including *Boxed Warning* FDA's most prominent warning, for tofacitinib, baricitinib and upadacitinib to include information about the risks of serious heart-related events, cancer, blood clots, and death. Recommendations for health care professionals will include consideration of the benefits and risks for the individual patient prior to initiating or continuing therapy. In addition, to ensure the benefits of these three medicines outweigh the risks in patients who receive them, FDA is limiting approved use to certain patients who have not responded or cannot tolerate one or more TNF blockers.

US-FDA requests removal of strongest warning against using statins during pregnancy[1]

A contraindication is FDA's strongest warning and is only added when a medicine should not be used because the risk clearly outweighs any possible benefit. FDA requests removal of strongest warning against using cholesterol-lowering statins during pregnancy but still advises most pregnant patients should stop taking statins. Breastfeeding is not recommended in patients who require statins. Because the benefits of statins may include prevention of serious or potentially fatal events in a small group of very high-risk pregnant patients, contraindicating these drugs in all pregnant women is not appropriate.

FDA expects removing the contraindication will enable health care professionals and patients to make individual decisions about benefit and risk, especially for those at very high risk of heart attack or stroke. This includes patients with homozygous familial hypercholesterolemia and those who have previously had a heart attack or stroke. Statins are safe to use in patients who are not pregnant but may become pregnant.

Methotrexate – Progressive multifocal leukoencephalopathy (PML)[2]

Having considered the available evidence in EudraVigilance, the literature, and clinical data, the The Pharmacovigilance Risk Assessment Committee recommended to update Summary of Product Characteristics of methotrexate with addition of following text in Special Warning and Precaution section "Cases of PML have been reported in patients receiving methotrexate, mostly in combination with other immunosuppressive medication. PML can be fatal and should be considered in the differential diagnosis in immunosuppressed patients with new onset or worsening neurological symptoms".

Drug Safety Alerts by PvPI Database[3] from Jul to Sep 21

Suspected Drug	Indication	ADRs
Etoricoxib	Pain, swelling & inflammatory conditions due to arthritis	Acute Generalized Exanthematous Pustulosis
Torsemide	Oedema associated with congestive heart failure & hypertension	DRESS Syndrome
Sofosbuvir	Chronic hepatitis C in adults	Stevens-Johnson Syndrome
Dimethyl Fumarate	Relapsing remitting multiple sclerosis	Alopecia
Cefazolin	Serious infections due to susceptible organisms – LRTI, UTI, skin infections, billiary tract infections, septicaemia	Acute Generalized Exanthematous Pustulosis

Source

1. US Food and Drug Administration. Drug Safety Communications. Last accessed on 07 Oct 2021 (https://www.fda.gov/drugs/drug-safety-and-availability/drug-safety-communications)
2. Pharmacovigilance Risk Assessment Committee (PRAC). European Medicines Agency. Last accessed on 07 Oct 2021 (https://www.ema.europa.eu/en/human-regulatory/post-authorisation/pharmacovigilance/signal-management/prac-recommendations-safety-signals)
3. Pharmacovigilance Programme of India (PvPI) Updates. Last accessed on 07 Oct 2021 (https://www.ipc.gov.in/mandates/pvpi/pvpi-updates/8-category-en/416-drug-safety-alerts.html)

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Department of Pharmacology, Armed Forces Medical College, Pune

Adverse Drug Reaction Monitoring Centre(AMC)
under the aegis of Pharmacovigilance Programme of India
Indian Pharmacopoeia Commission, Ghaziabad
have celebrated

NATIONAL PHARMACOVIGILANCE WEEK (17th – 23th Sep)

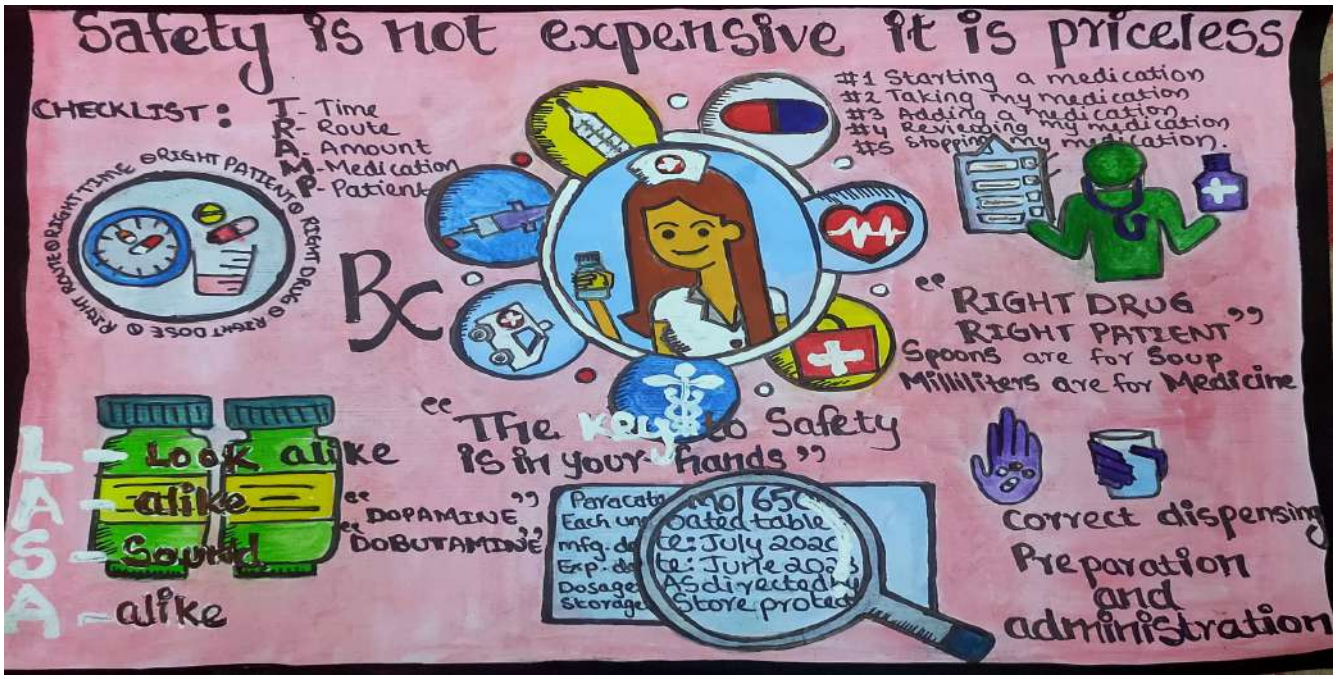
SENSITIZATION PROGRAMME AND HANDS ON EXERCISE ON ADR REPORTING
TARGET AUDIENCE- NURSING CADETS AND PARAMEDICAL STAFF
Total 180 attended.

E-QUIZ COMPETITION FOR PGS AND UGS

SENSITIZATION OF PATIENTS TOWARDS MEDICATION SAFETY
Carried out in OPD and Wards.

E-POSTER COMPETITION:
CATEGORIES:
A)UGs AND Nursing cadets
B)Paramedical trainees
THEME: Prevention of medication error and promotion of medication safety

Winner of E-Poster Competition



You are requested to report any observed ADRs to Dept of Pharmacology, ADR monitoring centre with following mode of communication:

1. **ADR form (Version 1.4) can be downloaded from IPC website. Link: https://www.ipc.gov.in/PvPI/adr.html**
2. **Contact Number: 7385666876**
3. **Email-ID: pvpiafmc@gmail.com**
4. **Google Form Link: https://docs.google.com/forms/d/e/1FAIpQLSfFWfSHemNQ56a3Pz5rfKe-jfZ2oumA0Xs_3kO4iYcs0-mr5Q/formResponse**

Any Person ADR Any Time
Any Drug