Review Article

Pharmacovigilance in the Era of Modern Medicine: Surveillance, Alerts and Black Box Warnings

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Abstract:

Background: Pharmacovigilance (PV) is a critical public health discipline focused on the detection, evaluation, and prevention of adverse drug reactions (ADRs) and other drug-related problems. Its significance has intensified in the modern era, with increasing drug complexity, widespread use of biologics, and expanding post-marketing surveillance needs. **Objective:** To review the current landscape of pharmacovigilance, highlight recent drug safety alerts and black box warnings, and assess the integration of pharmacovigilance systems in India, with a regional focus on activities in Meerut. **Methods:** This article presents a narrative review of pharmacovigilance practices and regulatory alerts. It includes recent safety data from national and international authorities such as WHO, US-FDA, EMA, and India's IPC. Data on drug safety alerts (2024–2025) and black box warnings were compiled and analyzed to demonstrate real-world pharmacovigilance activity. **Results:** Multiple drug safety alerts were issued by IPC in 2024–2025, identifying severe ADRs like AGEP, DRESS syndrome, and leukopenia linked to commonly prescribed drugs. Black box warnings from the US-FDA were also reviewed, involving high-risk drugs. India's PvPI and MvPI have strengthened national vigilance, with Subharti Medical College serving as a key ADR monitoring center in western Uttar Pradesh. **Conclusion:** Pharmacovigilance remains vital in ensuring patient safety amid evolving therapeutic landscapes. Strengthening global and national surveillance, rapid dissemination of drug alerts, and promoting healthcare professional education are essential for minimizing drug-related risks and enhancing clinical outcomes.

Keywords: Pharmacovigilance, Adverse Drug Reactions, Black Box Warning, Drug Safety Alerts, PvPI, MvPI, Subharti Medical College, FDA, IPC, Patient Safety.

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Pharmacovigilance (PV) is the science and activities concerned with the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems.[1]It serves as a key component in ensuring drug safety throughout a product's life cycle—from pre-marketing clinical trials to post-marketing surveillance. With the global expansion of the pharmaceutical industry and the increasing complexity of drug therapies, the role of pharmacovigilance has become more crucial than ever. [1;2]

The **primary objective** of pharmacovigilance is to improve patient care and safety in relation to the use of medicines and to support public health programs by providing reliable, balanced information for the effective assessment of the risk-benefit profile of drugs. [1;2]

Adverse drug reactions (ADRs) and medication errors are among the leading causes of morbidity and mortality worldwide. Hence, a robust pharmacovigilance system helps in minimizing risks, promoting rational drug use, and enhancing therapeutic outcomes. [2,3]

Global organizations such as the World Health Organization (WHO), European Medicines Agency (EMA), and national regulatory authorities have emphasized the integration of pharmacovigilance practices into healthcare systems. [1,2] In India, **the Pharmacovigilance Programme of India (PvPI),** launched by the Ministry of Health and Family Welfare, plays a pivotal role in collecting and analyzing ADR reports to ensure patient safety and strengthen drug regulation.[4]

As healthcare continues to evolve with advancements in biotechnology, personalized medicine, and the use of artificial intelligence in healthcare, pharmacovigilance must adapt accordingly. This article explores the principles, current practices, challenges, and future directions in pharmacovigilance, highlighting its indispensable role in modern therapeutics.

Pharmacovigilance and its impact in medicine

Pharmacovigilance began globally after the thalidomide tragedy in the 1960s, which caused severe birth defects and highlighted the need for drug safety monitoring. In response, the World Health Organization (WHO) launched the International Drug Monitoring Programme in 1968, with VigiBase as the global ADR database.

In India, pharmacovigilance officially began in 2004 with the launch of the National Pharmacovigilance Programme (NPvP), later renamed as the Pharmacovigilance Programme of India (PvPI). The National coordination centre (NCC) for the PvPI is

the Indian Pharmacopoeia Commission (IPC), located in Ghaziabad, Uttar Pradesh.

In Meerut, the Pharmacovigilance Adverse Drug Reaction (ADR) Monitoring Centre (AMC) is in Pharmacology Department, Netaji Subhash Chandra Bose Subharti Medical College, affiliated with Swami Vivekanand Subharti University. We report adverse drug events received from LLRM Medical college and reports filled by healthcare personnels of hospitals of NCR.

Since 24 January 2014 the institution has played an active role in promoting drug safety and awareness, and it also offers a certificate course in the basics of Pharmacovigilance and Materiovigilance, reflecting its commitment to strengthening pharmacovigilance practices in the region.

Materiovigilance is a system for monitoring and preventing adverse events related to the use of medical devices. It involves identifying, collecting, reporting, and analyzing any untoward occurrences associated with medical devices, with the goal of improving patient safety and preventing future incidents. [5]

The MateriovigilanceProgramme of India (MvPI) was formally launched at the Indian Pharmacopeia Commission (IPC), Ghaziabad by the Drugs Controller General India (DCGI) on July 06, 2015. Indian Pharmacopoeia Commission (IPC) is an autonomous institution of the Ministry of Health & Family welfare and also functions as the National Coordination Centre (NCC) for the MateriovigilanceProgramme of India. Sree Chitra Tirunal Institute of Medical Sciences & Technology (SCTIMST), Thiruvananthapuram functions as a National Collaborating Centre for the MvPI. Technical support for the programme is being provided by Healthcare Technology Division, National Health System Resource Centre (NHSRC), New Delhi which is also a WHO collaborating Centre for priority medical devices and health technology policy.[5]

In Meerut since July 2021, the Medical Device Adverse Event Monitoring Centre (MDMC) is Department of Pharmacology, Netaji Subhash Chandra Bose Subharti Medical College, affiliated with Swami Vivekanand Subharti University.

Ensuring the safety of medications is a critical component of public health and clinical practice. Despite rigorous testing and regulatory approval processes, many drugs may exhibit unforeseen adverse effects once they are introduced to a broader patient population. **Drug safety alerts** play a pivotal role in identifying, communicating, and managing these post-marketing risks. These alerts are issued by national and international regulatory authorities—such as the World Health Organization (WHO), U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA), and Central Drugs Standard Control Organization (CDSCO) in India—based on new safety data from pharmacovigilance systems, spontaneous reports, clinical studies, or epidemiological research. [6,7]

Drug safety alerts are designed to inform healthcare professionals, patients, and stakeholders about significant safety concerns, including new adverse drug reactions (ADRs), contraindications, drug–drug interactions, or product recalls. These alerts aim not only to minimize harm but also to reinforce the safe and effective use of medicines in clinical settings.

Table 1: Various drug safety alerts issued by IPC in year 2024 and 2025 [5]

Month	Suspected Drug	Indication	ADR
May 2024	Meropenem	For treatment of pneumonia, nosocomial pneumonia, UTI, intra-abdominal infection, gynecological infection, skin & soft tissue infection, meningitis, septicemia & empiric treatment of presumed infection in adult patients with febrile neutropenia.	Acute Generalized Exanthematous Pustulosis (AGEP)
June 2024	Acetazolamide	As an adjunct in the treatment of Choroidal effusion chronic open-angle glaucoma; secondary glaucoma; as part of pre-operative treatment of acute-angle closure glaucoma.	Choroidal effusion or Choroidal detachment
July 2024	Vancomycin Amlodipine	Treatment of serious infection due to Gram-positive cocci including methicillin-resistant staphylococcal infections, staphylococcal brain abscess, meningitis and septicemia. To reduce fatal coronary heart disease and non-fatal myocardial infarction, and to reduce the risk of stroke. To reduce the risk of coronary revascularization procedures and need for hospitalization due to angina in patients with coronary artery diseases	Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) Syndrome. Lichenoid Keratosi
August 2024	Metronidazole	For the treatment of amoebiasis, urogenital trichomoniasis & giardiasis	Fixed Drug Eruption (FDE)

September 2024	Tetracycline	Treatment of Rocky Mountain spotted fever, typhus, Q fever, rickettsial pox, tick fever caused by Rickettsiae, respiratory tract infections caused by Mycoplasma pneumonia, Chlamydia infection, nongonococcal urethritis, chancroid, plague, tularemia, cholera, brucellosis, bartonellosis, granuloma inguinale, haemophilus and kleibsella infections, psittacosis.	Fixed Drug Eruption
Nov 2024	Amphotericin B Carbimazole	1. Treatment of Febrile Neutropenia in cancer patients. 2. Treatment for invasive fungal infection inpatients, who are refractory to or intolerant conventional Amphotericin of therapy. 3. Indicated for the treatment of Visceral Leishmaniasis. Indicated for the treatment of thyrotoxicosis including thyrotoxicosis crisis.	Hyperkalaemia Agranulocytosis
Dec 2024	Beta-blockers (Metoprolol, Propranolol, Atenolol)	**Metoprolol:** For the treatment of essential hypertension in adults, functional heart disorders, migraine prophylaxis, cardiac arrhythmias, prevention of cardiac death and reinfarction after the acute phase of myocardial infarction,stable symptomatic CHF and angina pectoris. **Propranolol:** For the treatment of cardiac arrhythmias ; tachycardia; hypertrophic obstructive cardiac myopathy ;pheochromocytoma; thrombosis; management of angina; essential and renal hypertension; prophylaxis of migraine. **Atenolol:** For the treatment of hypertension, angina pectoris, cardiac arrhythmias.	Hypokalemia
March 2025	Metronidazole Luliconazole Dalteparin Gliclazide Tramadol	For the treatment of amoebiasis, urogenital trichomoniasis & giardiasis. For the treatment of cutaneous mycosis viz. Tinea pedis, Tinea corporis and Tinea cruris. For the extended treatment of symptomatic VenousThromboembolism(VTE) proximal Deep Vein Thrombosis(DVT) and/or Pulmonary Embolism (PE) to reduce the recurrence of VTE in patients with cancer. Indicated for the treatment of all types of maturity onset diabetes, diabetes without or with obesity in adults. For the treatment of severe acute and chronic pain, diagnostic measures and surgical pain.	Acute Generalised Exanthematous Pustulosis (AGEP) Chloasma/Melasma Muscle spasms Erythema multiforme Fixed Drug Eruption
May 2025	Sulfamethoxazole + Trimethoprim	For the treatment of Urinary Tract infection; Respiratory-tract infection including Bronchitis, Pneumonia, infections in Cystic Fibrosis, Melioidosis, Listeriosis, Brucellosis, Granuloma Inguinale, Otitis Media, Skin infection, Pneumocystis Carinii Pneumonia	Leukopenia

A Black Box Warning

They are most serious alert issued by the U.S. FDA. Are used to highlight drugs that carry a significant risk of severe or life-threatening adverse effects. Displayed with a bold black border in the drug's prescribing information, it serves as a clear warning to prescribers and patients. [2,7]

While such drugs may offer important therapeutic benefits, they require extra caution, monitoring, and informed decision-making

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Table 2: Drugs which have been issued black box warning recently

S.No	Drug Name	Warning
1	CAR-T Therapies (e.g., Abecma, Carvykti, Tecartus)	Risk of secondary malignancies
2	Prolia (denosumab)	Severe hypocalcemia in CKD patients
3	Ocaliva (obeticholic acid)	Serious liver injury (especially without cirrhosis)
4	Veozah (fezolinetant)	Rare serious liver toxicity
5	Glatiramer acetate (Copaxone, Glatopa)	Risk of anaphylaxis
6	Trikafta (elexacaftor/tezacaftor/ivacaftor)	Serious and fatal liver injury
7	Fenfluramine	Cardiopulmonary risks
8	Lamotrigine	Neonatal withdrawal, drug reaction with eosinophilia
9	Gabapentin, Pregabalin	Interaction with hormones, withdrawal symptoms
10	Zenocutuzumab (Bizengri)	Embryo-fetal toxicity

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