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Why Drug Safety Has Become India's Next Pharmaceutical Imperative

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India's pharmaceutical industry has built its global reputation on affordable medicines and large-scale manufacturing, but drug safety is emerging as its next defining challenge. Recent recalls, quality failures and medication errors have exposed vulnerabilities that extend beyond manufacturing to pharmacovigilance, supply-chain integrity, regulatory transparency and post-market surveillance. As India expands its role as the "pharmacy of the world," strengthening every layer of the drug safety ecosystem has become essential to protecting patients, preserving global trust and sustaining the country's pharmaceutical leadership.



Drug safety has come under renewed scrutiny as regulators in India and overseas step up surveillance beyond manufacturing compliance. Within weeks, Lupin's recall of more than 2.5 million bottles of an ophthalmic product in the United States, Maharashtra Food and Drug Administration's action against Cadila Pharmaceuticals' Aciloc products, and the Central Drugs Standard Control Organisation's (CDSCO) latest quality alerts have underscored the growing focus on contamination, medication errors and post-market surveillance.

The latest action comes from the United States, where Lupin Pharmaceuticals, the US subsidiary of Lupin Limited, voluntarily recalled 2,530,182 bottles of Prednisolone Acetate Ophthalmic Suspension USP 1 per cent, a prescription corticosteroid eye drop used to treat steroid-responsive eye inflammation. Initiated on June 4, the recall was later classified by the US Food and Drug Administration (FDA) as a Class II recall, indicating that use of the product may cause temporary or medically reversible health effects, with a remote risk of serious injury.

Manufactured at Lupin's Pithampur facility in Madhya Pradesh and distributed nationwide in the US, the affected 5 mL, 10 mL and 15 mL bottles were recalled due to the "presence of foreign substance." Although the FDA has not identified the contaminant, reports suggest the action followed a market complaint involving foreign particulate matter that could potentially cause mechanical irritation, corneal injury or ocular inflammation. No adverse events have been reported to date.

The product was approved through the abbreviated new drug application (ANDA) pathway in 2024 as the generic equivalent of Pred Forte. The recall also adds to Lupin's recent regulatory history, following its 2023 recall of oral contraceptive pills and multiple FDA inspection observations at its Indian manufacturing facilities.

In India, regulators recently highlighted another dimension of drug safety—preventing medication errors. The Maharashtra Food and Drug Administration (FDA) prohibited the sale and distribution of selected gastrointestinal medicines manufactured by Cadila Pharmaceuticals Ltd. and ordered the recall of stocks worth around Rs 2.45 crore. The action covers Aciloc 150 and Aciloc 300, containing ranitidine, and Aciloc 150 Plus and Aciloc 300 Plus, containing famotidine. Despite containing different active ingredients, the products shared nearly identical branding and packaging, distinguished only by a small "+" symbol. According to Maharashtra FDA, the similarity posed a significant risk of dispensing and prescribing errors, reinforcing that patient safety depends not only on medicine quality but also on clear labelling and product differentiation.

Dr Arani Chatterjee, President, Cadila Pharmaceuticals while reaffirming commitment to patient safety and regulatory compliance said, "Patient safety remains our highest priority. The active pharmaceutical ingredient is clearly stated on every Aciloc pack in accordance with applicable regulatory requirements. We are working closely with the relevant authorities, extending our full cooperation and reviewing the matter carefully. We remain committed to ensuring continued confidence in the quality, safety and appropriate use of our medicines."

Drug quality concerns have also come under intense scrutiny following the deaths of five new mothers in Kota after childbirth, allegedly linked to oxytocin injections that reportedly contained only water instead of the active ingredient. The incident, which remains under investigation, has intensified questions around manufacturing quality, regulatory oversight and supply-chain integrity. Although unrelated to the Lupin and Aciloc cases, the tragedy illustrates the potentially devastating consequences of failures in medicine quality.

Meanwhile, CDSCO's May 2026 Drug Alert identified 157 drug samples as Not of Standard Quality (NSQ) and two samples as spurious following routine testing by Central and State Drug Testing Laboratories. The list included antibiotics, anti-diabetic medicines, cardiovascular drugs, gastrointestinal products, injectables and medical devices that failed quality parameters

such as dissolution, assay, sterility, microbial contamination, particulate matter and related substances. Manufacturers whose batches appeared in the latest alert included Sun Pharmaceutical Industries, Alkem Laboratories, Cipla, Macleods Pharmaceuticals, Medreich, Blue Cross Laboratories, Cadila Pharmaceuticals and Taj Pharma India, among others.

The May alert forms part of a sustained surveillance programme throughout 2026, with CDSCO identifying 215 NSQ samples in January, 194 in February, 141 in March, 120 in April and 157 in May, along with a small number of spurious drugs. These monthly inspections and recalls reflect a more proactive regulatory approach aimed at identifying quality lapses before they affect larger patient populations.

Collectively, these developments point to a broader reality: ensuring drug safety today requires far more than manufacturing compliance. Product quality, packaging, pharmacovigilance, rapid recalls and transparent regulatory communication have all become integral to patient safety. While regulators have strengthened enforcement, experts believe important gaps remain, prompting calls for greater transparency, stronger pharmacovigilance systems and closer coordination across the healthcare ecosystem.

Calling for Stricter Regulations

Reports suggest that India's drug regulators may soon publicly disclose the names of pharmaceutical companies facing serious enforcement action, including licence suspension, cancellation and drug recall orders, under a proposed transparency initiative aimed at strengthening the country's medicine safety framework. An expert committee constituted by CDSCO has also recommended that state drug regulators publish enforcement actions on their official websites and submit monthly reports to the central regulator.

Despite these initiatives, industry experts believe significant gaps remain in enforcement, communication and pharmacovigilance, limiting the effectiveness of India's drug safety ecosystem.

Dr Subhash C Mandal, National Honorary General Secretary, Indian Pharmaceutical Association (IPA), believes that a stronger pharmacovigilance system is fundamental to improving medicine safety. "Although pharmacovigilance activities began in India in 1989, a structured national system was established only later. Initially, adverse drug reaction (ADR) reporting was voluntary and industry participation remained limited. Subsequent regulatory changes have made reporting mandatory to a certain extent. IPA continues to work towards improving patient awareness, advocating policy reforms and training pharmacists across different healthcare settings," he says.

According to Dr Mandal, IPA also encourages patients and their caregivers to report adverse events through the online ADR reporting portal, nearby Adverse Drug Reaction Monitoring Centres (AMCs), or directly to the Pharmacovigilance Programme of India (PvPI) at the Indian Pharmacopoeia Commission.

Another area of concern is the timely communication of recalls and safety alerts. The All India Organisation of Chemists and Druggists (AIOCD), representing nearly 12.4 lakh members, has consistently raised concerns over illegal and unregulated e-pharmacy platforms, arguing that they often fail to comply with prescription verification, traceability, storage standards and patient counselling requirements.

Rajiv Singhal, General Secretary, AIOCD, says, "There have been improvements in regulatory communication; however, recall notices, safety alerts and product withdrawal information often remain confined to websites or official notifications and do not always reach pharmacists, distributors and retailers across the country in time. Through our nationwide network, AIOCD immediately disseminates such information to stakeholders."

Singhal believes India now needs a centralised real-time recall communication system, supported by digital alerts, SMS notifications, emails and mandatory recall tracking mechanisms that seamlessly connect CDSCO, state regulators, manufacturers, distributors and pharmacy associations.

Sarvesh Singh, CEO, Telangana Life Sciences, believes India still contributes a disproportionately small share of global adverse drug reaction reports despite being the world's third-largest pharmaceutical producer by volume. "Challenges such as under-reporting of adverse drug reactions, limited awareness among healthcare professionals and patients, and inadequate use of digital technologies and real-world evidence continue to restrict the effectiveness of India's pharmacovigilance ecosystem," he says.

Role of Clinicians in Pharmacovigilance

Doctors remain central to strengthening pharmacovigilance by prescribing medicines rationally, following evidence-based treatment guidelines and promptly reporting suspected adverse drug reactions.

Prof (Dr) Subhrojyoti Bhowmick, Vice President-Clinical Services and Quality, ILS Group of Hospitals, Kolkata believes drug safety practices will undergo a major transformation over the next five years. "We are likely to witness stronger post-marketing surveillance, wider adoption of active pharmacovigilance, greater use of artificial intelligence and real-world evidence, better integration of electronic health records with national safety databases, and greater patient participation in reporting adverse events," he says.

Strengthening Pharmacovigilance

Close collaboration among regulators, pharmaceutical companies, researchers, healthcare providers and investigators will be essential to improve patient safety throughout a medicine's lifecycle.

Sanjay Vyas, President, Global Head-Clinical Logistics and Patient Safety & Pharmacovigilance and Managing Director, Parexel, believes increasing awareness and encouraging timely reporting of adverse events remain among the industry's biggest priorities. "The more complete and higher quality the safety data, the better equipped regulators and companies are to identify emerging risks and take timely action. Continued investments in digital capabilities, skilled talent and standardised processes will strengthen pharmacovigilance and ultimately benefit patients," he says.

India's pharmacovigilance ecosystem is entering a more mature phase of regulation, with increasing emphasis on accountability, compliance and lifecycle safety monitoring. Industry experts also believe specialised pharmacovigilance service providers have an increasingly important role in strengthening compliance and signal detection.

Dr J Vijay Venkatraman, MD and CEO, Oviya MedSafe, says the fragmented nature of India's pharmaceutical industry remains one of the biggest challenges. "Many companies continue to view pharmacovigilance as a compliance cost associated primarily with innovative medicines. However, even products that have been in use for decades can generate new safety signals when monitored systematically. Another challenge is ambiguity over whether responsibility lies with the legal Marketing Authorisation Holder or the company marketing the product, resulting in gaps in accountability," he explains.

He notes that leading pharmaceutical companies have moved beyond treating pharmacovigilance as a regulatory obligation by investing in dedicated safety teams, digital technologies, signal detection and continuous benefit-risk monitoring.

Dr Girish Bassavaraju, Country Head-Global Business Operations, Cosette Pharmaceuticals adds, "The objective should not merely be regulatory compliance. Companies must proactively identify safety signals, assess risks and take timely actions that protect patients."

Can AI Transform Drug Safety?

Artificial intelligence is increasingly emerging as an important enabler of modern pharmacovigilance. AI algorithms can continuously analyse structured and unstructured data from electronic health records, spontaneous reporting systems, scientific literature and patient registries to identify emerging safety signals much earlier than conventional methods.

Natural language processing can automate the analysis of adverse event narratives across multiple languages, significantly reducing case-processing time. This capability is particularly valuable for Indian pharmaceutical companies supplying regulated markets, where reporting timelines are stringent and delayed signal detection can carry significant regulatory consequences.

Singh believes pharmacovigilance must evolve from a regulatory obligation into a proactive, technology-enabled patient safety function supported by AI, real-world evidence and stronger collaboration across healthcare stakeholders. Parexel also views AI as an enabler that complements rather than replaces human expertise. Through its ParexelAI platform, the company reports a 20 per cent reduction in safety literature screening and pharmacovigilance case processing time.

Several technology companies are also developing AI-enabled pharmacovigilance platforms to automate safety monitoring and improve regulatory compliance.

Abhishek Rungta, Founder and CEO, Indus Net Technologies (INT.), believes agentic AI, large-scale real-world data integration and digital twin technologies will fundamentally transform pharmacovigilance over the next five years. However, he cautions that India continues to face persistent under-reporting of adverse drug reactions and inconsistent data quality across reporting centres, limiting national signal detection capabilities.

Similarly, Nirnasa is developing AI-powered solutions for Individual Case Safety Report (ICSR) processing, MedDRA coding and signal detection. According to **P Shiva Raghava Rao, Managing Director, Nirnasa,** fragmented safety systems and manual workflows continue to increase the risk of reporting delays and compliance gaps.

Need for Coordinated Action

Patient safety can only be ensured through a coordinated drug safety ecosystem involving CDSCO, State Drug Controllers, pharmaceutical manufacturers, distributors, pharmacists, healthcare professionals and industry associations, with each stakeholder assuming clearly defined responsibilities.

Reflecting this collaborative approach, the Indian Pharmacopoeia Commission (IPC) signed Memoranda of Understanding in February 2026 with the Goa State Pharmacy Council, the Quality Council of India and HLL Infra Tech Services Limited to strengthen pharmacovigilance, quality assurance and capacity building. Although currently focused on Goa, the initiative could serve as a model for similar collaborations across other states.

The Road Ahead

Recent recalls, quality alerts and enforcement actions demonstrate that drug safety can no longer be viewed solely as a regulatory obligation. It demands coordinated action across regulators, pharmaceutical companies, healthcare professionals, pharmacists, distributors and technology partners. As India strengthens its position as the "pharmacy of the world," enhancing pharmacovigilance, improving recall communication, leveraging AI-enabled safety surveillance and ensuring supply-chain integrity will be critical. Even a handful of preventable incidents can erode patient confidence and damage India's reputation as a trusted global supplier of safe, affordable and high-quality medicines.

Sanjiv Das

sanjiv.das@mmactiv.com