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• IPC continues to strengthen pharmacovigilance through the adoption of digital technologies •

01 August 2026 | Views | By Sanjiv Das

In an exclusive interview with BioSpectrum India, Dr V Kalaiselvan, Secretary-cum-Scientific Director, Indian Pharmacopoeia Commission (IPC), Ministry of Health & Family Welfare, Government of India, outlines the IPC's role in safeguarding drug quality and ensuring medicine safety through a robust pharmacovigilance framework.



How does IPC ensure that medicines marketed in India meet the required standards of quality, safety, and efficacy?

The Indian Pharmacopoeia Commission (IPC), an autonomous institution under the Ministry of Health and Family Welfare, Government of India, contributes to ensuring the quality, safety, and efficacy of medicines through the development and publication of the Indian Pharmacopoeia (IP), which prescribes legally enforceable standards for drug substances, dosage forms, excipients, biological products, vaccines, blood and blood products, and medical devices. IPC also develops and supplies Indian Pharmacopoeia Reference Standards (IPRS) that support quality testing by manufacturers, regulatory laboratories, and other stakeholders.

The continuous revision of the Indian Pharmacopoeia and development of scientifically validated reference standards support the Government of India's commitment to ensuring access to safe, effective, and quality-assured medicines under the vision of Viksit Bharat @2047 and contribute towards strengthening India's pharmaceutical quality ecosystem.

While IPC establishes scientific standards for quality and coordinates the Pharmacovigilance Programme of India (PvPI) for monitoring medicine safety, the regulatory approval, licensing, and enforcement functions are carried out by the Central Drugs Standard Control Organisation (CDSCO) and the respective State Drug Regulatory Authorities.

With recent concerns around banned or withdrawn drug formulations, what role does IPC play in identifying safety signals?

Under the PvPI, IPC serves as the National Coordination Centre (NCC) for collecting, analysing, and evaluating reports of suspected adverse drug reactions (ADRs) received from a nationwide network of Adverse Drug Reaction Monitoring Centres (AMCs), healthcare professionals, pharmaceutical companies, and patients.

Potential safety signals identified through scientific signal detection and assessment are reviewed by subject experts. Where appropriate, evidence-based recommendations are submitted to CDSCO for regulatory consideration, including updates to prescribing information, safety communications, or other regulatory actions. Decisions regarding market restrictions, withdrawals, or bans are taken by the national drug regulator based on the totality of available scientific evidence.

Is IPC using artificial intelligence, automation, or digital tools to improve pharmacovigilance surveillance?

IPC continues to strengthen pharmacovigilance through the adoption of digital technologies. The Adverse Drug Reaction Monitoring System (ADRMS) enables electronic reporting, data management, and analysis of ADRs across the country. The ADR PvPI Mobile Application further facilitates timely reporting by healthcare professionals and consumers.

These digital initiatives align with the Government of India's Digital India mission by promoting technology-enabled healthcare governance, improving accessibility to ADR reporting, and enabling more efficient pharmacovigilance activities across the country.

What are the key priorities for IPC to strengthen India's drug safety framework over the next five years?

The IPC is focused on expanding the pharmacovigilance network to achieve broader geographical and institutional coverage while improving the quality and timeliness of ADR reporting through stronger stakeholder engagement and capacity building. It is also prioritising the use of digital technologies and advanced data analytics to enhance signal detection and risk assessment.

In parallel, IPC aims to strengthen collaboration with national and international regulatory agencies, academic institutions, healthcare professionals, and the pharmaceutical industry. Increasing patient awareness and encouraging greater consumer participation in ADR reporting remain important priorities. The Commission is also working to further harmonise Indian pharmacopoeial standards and pharmacovigilance practices with globally accepted scientific and regulatory frameworks.

Through these initiatives, IPC remains committed to strengthening India's medicine safety ecosystem by advancing scientific excellence, providing robust regulatory support, fostering stakeholder collaboration, and driving continuous innovation.

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