

**REGULATORY REQUIREMENTS ON PHARMACOVIGILANCE AS PER CDSCO IN
INDIA COMAPARISON WITH NEW ZEALAND****Dr. P. Ashok Kumar P.*, Prajwal S., Yogananda D. M., Pavan C., Shivashankar H. R., Nayana B. R.**Department of Regulatory Affairs, Sree Siddaganga College of Pharmacy Tumakuru-572103 Karnataka, India,
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[Affiliated to Rajiv Gandhi University of Health Sciences, Bengaluru].DOI: <https://doi.org/10.5281/zenodo.23032644>**How to cite this Article:** Dr. P. Ashok Kumar P.*, Prajwal S., Yogananda D. M., Pavan C., Shivashankar H. R., Nayana B. R. (2026). Regulatory Requirements on Pharmacovigilance As Per Cdsco In India Comaparison With New Zealand. European Journal of Pharmaceutical and Medical Research, 13(10), 283-287.This work is licensed under [Creative Commons Attribution 4.0 International license](https://creativecommons.org/licenses/by-nc/4.0/).

Article Received on 02/09/2026

Article Revised on 22/09/2026

Article Published on 01/10/2026

ABSTRACT

Pharmacovigilance is an essential component of medicine safety that involves the Detection, assessment, understanding, and prevention of adverse drug reaction and other medicine-related problems. In India CDSCO regulates post-marketing drug safety activities through requirements for marketing authorization holders [MAHs], individual case safety reports [ICSRs], periodic safety update reports [PSURs], signal detection, risk management, and pharmacovigilance system. CDSCO'S current post-marketing framework includes guidance for MAHs and electronic PSUR submission through the SUGAM portal. In New Zealand pharmacovigilance is regulated primarily by Medsafe with safety monitoring supported by the center for adverse reactions monitoring. Sponsors are required to maintain system for collecting and evaluating adverse reaction information and to report valid serious ICSRs occurring in New Zealand generally within 15 days calendar days of receipt the comparison examines regulatory authorities ADR/ICSR reporting requirements, reporting timeline, safety monitoring, signal detection, and responsibilities of pharmaceutical companies. Overall the study highlights similarities and differences in the two national systems and emphasizes and importance of effective post-marketing surveillance for ensuring the continued safe and rational use of medicines

KEYWORDS: Pharmacovigilance, CDSCO, Medsafe, Adverse Drug Reaction, ADR Reporting.**INTRODUCTION**

Pharmacovigilance is the sciences and activities concerned with the detection assessment understanding and prevention of adverse effects or any other drug-related problems. It plays an important role in protecting public health by continuously monitoring the safety of medicines undergo extensive evaluation before approval clinical trials have limitation because they involve relatively small and selected population and may not detect all rare or long-term adverse reaction therefore continuous post-marketing safety monitoring is essential.

In India pharmacovigilance is regulated through the CDSCO under the ministry of health and family welfare government of India. The pharmacovigilance Programme of India [PvPI] supports the collection, assessment, and monitoring of adverse drug reactions through a network

of ADR monitoring centres. Marketing authorization holders [MAHs] also have responsibilities for maintaining pharmacovigilance systems collecting safety information evaluating adverse events detecting safety signals reports to the regulatory authority.

In New Zealand medicines are regulated by medsafe the New Zealand medicines and medical devices safety authority. Its pharmacovigilance framework involves spontaneous ADR reporting, safety monitoring evaluation of ICSR signal detection, risk management and regulatory action when necessary medicines sponsors are responsible for monitoring and reporting medicine safety information.

A comparison of India and New Zealand is useful because both countries aim to ensure the safe and

effective use of medicines but their regulatory structures reporting procedures responsibilities and safety monitoring requirements differ. This study therefore focuses in comparing the pharmacovigilance requirements of CDSCO in India with those of medsafe in New Zealand particularly with respect to ADR reporting ICSR requirements reporting timelines, signal detection, risk managements, and post marketing surveillance.^[1,2,3,4]

AIM AND OBJECTIVES

Aim: To study the regulatory requirements for pharmacovigilance in India under CDSCO and compare them with the pharmacovigilance system of New Zealand

Objectives

- Describes the concept, importance, and objectives of pharmacovigilance
- Review the Indian pharmacovigilance framework involving CDSCO PVPI, IPC, NCC, ADR monitoring centres
- Describes New Zealand's frameworks involving medsafe and CARM
- Compare ADR/ICSR reporting regulatory responsibilities and PMS requirements.^[5,6]

MATERIALS AND METHODS

Central Drug Standard Control Organization [CDSCO] India-regulatory guidance and post-marketing drug safety documents. CDSCO provides current guidance for marketing authorization holders [MAHs] including requirements related to pharmacovigilance system master files, Individual case safety reports [ICSRs] periodic safety update reports [PSURs] risk management plans quality management audit and inspection.

Pharmacovigilance Programme of India [PvPI] and the Indian pharmacopoeia commission [IPC] documents related to spontaneous ADR reporting and the functioning of ADR monitoring centres.

Medsafe, New Zealand the guideline on the regulation of therapeutic products in New Zealand part 8-pharmacovigilance and current guidance for sponsors in ADR reporting.

Relevant *scientific publications review articles and regulatory literature* available through recognized databases and official websites.

Methods: A comparative literature-review method was adopted. Information concerning the pharmacovigilance systems of India and New Zealand was collected reviewed and organized under common regulatory parameters. The following aspects were compared.

- Regulatory authorities and pharmacovigilance organization
- Responsibilities of marketing authorization holders
- ADR collection and reporting
- Requirements for valid ICSRs
- ICSR reporting timelines
- Periodic safety reporting
- Pharmacovigilance system and documentation
- Signal detection and safety evaluation
- Risk management activities literature monitoring
- Quality management audits and inspections
- Post-marketing safety surveillance

for India particular attention was given to the CDSCO regulatory framework and PvPI while for New Zealand the study focused on medsafe and the new Zealand pharmacovigilance database medsafe currently requires sponsors to submit valid serious ICSRs within 15 days of calendar days of receipt.^[2,4,5,6]

Overview of pharmacovigilance system in world

At the international level the world health organization[WHO] plays an important role in strengthening pharmacovigilance systems the WHO programme for international drug monitoring was established in 1968. Following concerns about medicine related adverse effects. The programme enables participating countries to share information on suspected ADR and supports international medicine-safety monitoring.

The Uppsala Monitoring Centre[UMC] in Sweden operates the WHO international pharmacovigilance database Vigibase which contains millions of ICSRs submitted by national pharmacovigilance centres.^[7,8]

Different countries have established national pharmacovigilance systems according to their regulatory frameworks ex: USA-FAERS, EUROPE-Eudravigilance under EMA, India-PvPI under CDSCO New Zealand-medsafe.

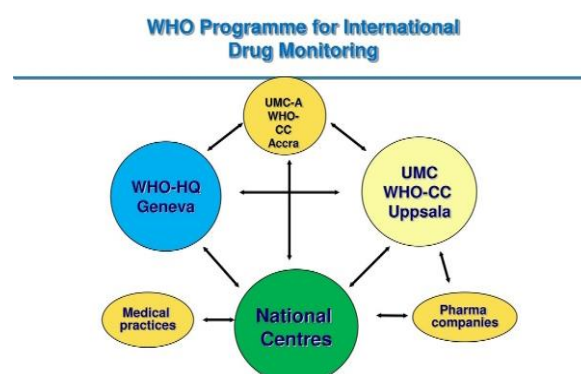


Figure no. 01: WHO International Drug Monitoring Programme.

RESULTS AND DISCUSSIONS: Comparative analysis**Table no 01: Comparison of Regulatory authorities.**

PARAMETERS	INDIA-CDSCO	NEW ZEALAND-MEDSAFE
Full Form	Central Drug Standard Control Organization	New Zealand medicines and medical devices safety authority
Ministry/Department	Ministry of health and family welfare: Government of India	Ministry of health, New Zealand
Headquarters	New Delhi	Wellington, New Zealand
Main Legislation	Drugs And Cosmetics Act 1940; drugs rules 1945, Medical devices rules 2017, NDCTR 2019	Medicines, Medical devices, related products and controlled drugs used as medicines
New Drug Approval	CDSCO approves new drugs and specified categories of product	Medsafe approves new and changed medicines and related product
Clinical Trails	Approves and regulates clinical trails	Approves clinical trails of new medicines
Main Objective	Ensure safety, efficacy, and quality, of medical products and uniform enforcement	Maximize safety and benefit of therapeutic products for new Zealand
Regulatory Structure	Decentralized/shared: CDSCO works with state drug control authorities	More centralized under medsafe and the ministry of health
Pharmacovigilance	Conduct pharmacovigilance and post market safety activities	Conducts pharmacovigilance surveillance and monitoring
Import Control	CDSCO regulates quality and import of drugs and medical devices	Medsafe performs border control and enforcement
Manufacturing Control	Central and state authorities share regulatory responsibilities	Medsafe audits and licenses medicine manufacturers

Table no. 02: Comparison of Pharmacovigilance system.

PARAMETERS	INDIA	NEW ZEALAND
National System	Pharmacovigilance Programme of India[PvPI]	New Zealand pharmacovigilance system
National Coordinating Body	Indian Pharmacopoeia Commission [IPC] Ghaziabad	Medsafe in collaboration with CARM
ADR Monitoring Centre	Network of ADR monitoring centres[AMC'S] throughout India	Centre for adverse drug reactions monitoring[CARM] university of Otago
Programme Started	PvPI Launches in 2010	CARM established in 1965
Main Objective	To protect the Indian population by monitoring ADR'S and ensuring that benefits of medicines outweigh risks	To detect medicines safety signals and protect the health of people using medicines and vaccines
ADR Reporting	Healthcare professionals and patients can report suspected ADRs	Anyone can report suspected adverse reaction
Reporting Method	ADR form, mobile apps, and ADR monitoring centres	Online ADR reporting with other reporting methods available
Signal Detection	Conduct within the PvPI system through it expert structures	Medsafe analyses ADR reports and other information to identify safety signals
International Collaboration	Participates in the who programme for international drug monitoring	New Zealand is along standing participant in the WHO programme for international drug monitoring
Data Management	Report are collected through AMC'S and processed through Vigiflow/Vigibase	Reports are collected and processes through the New Zealand pharmacovigilance database
Regulatory Action	CDSCO can take appropriate regulatory decision based on safety information	Medsafe can take regulatory/safety actions following risk-benefit assessment

Global pharmacovigilance market analysis

The global pharmacovigilance market was estimated by grand view research at approximately USD 8.6 billion in 2025 and USD 9.2 billion in 2026 with a projection of USD 13.5 billion by 2033 corresponding to a reported CAGR of 5.6% for 2026-2033. Market estimates vary considerably between research firms because they use different definitions, datasets, and market boundaries.^[9]

Regional Highlights

Largest Regional Market: North America [31.7% Revenue Share 2025]

Fastest Growing Regional Market : Asia Pacific [Fastest CAGR 2026-2033]

By Country : The U.S Held The Largest Market Share In 2025

Market Size And Forecast

Market Size In 2025: USD 8.6 Billion

Estimated Market Size in 2026 : USD 9.2 Billion

Projected Market Size By 2033: USD 13.5 Billion

CAGR [2026-2033]: 5.6%^[9]

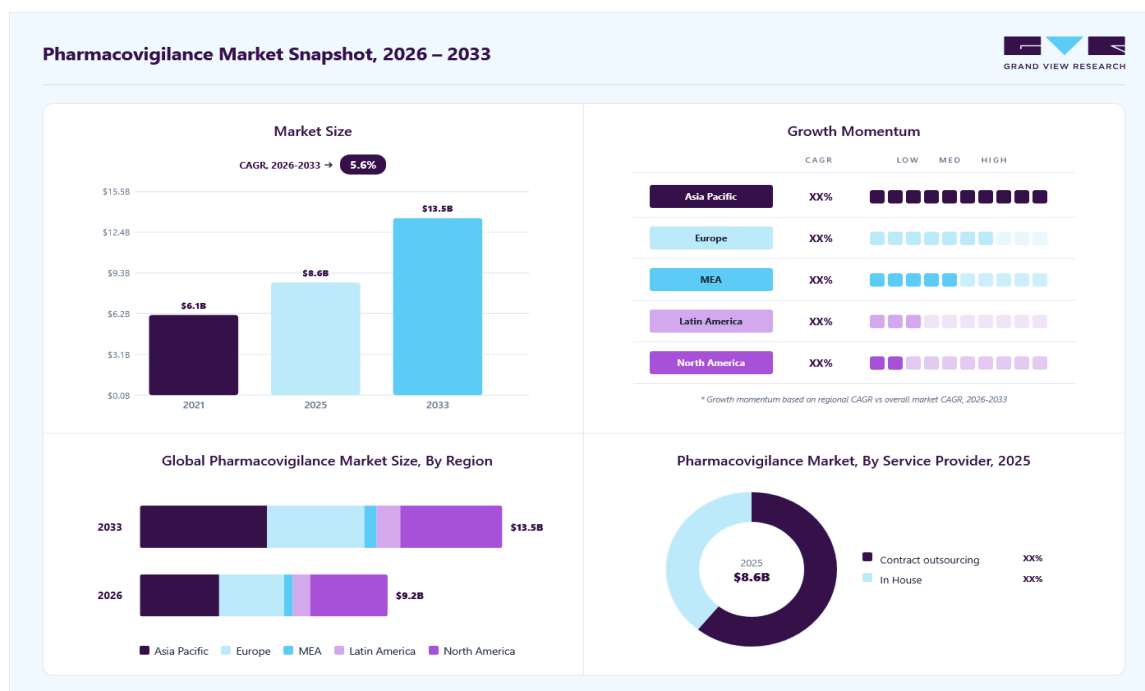


Figure No. 02: Pharmacovigilance Market Analysis Chart.

DISCUSSION

Future Trends in Pharmacovigilance

The future of pharmacovigilance is expected to become increasingly digital, data-driven patient-centered and proactive. Artificial intelligence and machine learning can help analyze large volumes of adverse drug reaction reports, electronics health records social media data and other real-world data to identify potential safety signals at an earlier stage. Automation and advanced data analytics may improve the speed and accuracy of ICSR processing, duplicate detection, case assessment and signal detection. Greater use of real world-evidence [RWE] and real world data will support continuous monitoring of medicines throughout their life cycle. Pharmacovigilance is also expected to make greater use of patient reported outcomes, mobile applications and digital reporting platforms, which can improve direct participation by patients and healthcare professionals

Overall future pharmacovigilance will gradually shift from a mainly reactive system based on reporting adverse events to a more proactive system capable of

predicting detecting and preventing medicines-related risks at an earlier stage.^[10,11,12]

CONCLUSION

Pharmacovigilance plays an essential role in ensuring the safe effective use of medicines by continuously monitoring adverse drug reaction and other medicine related safety concerns. The comparative evaluation of India and New Zealand demonstrates that both countries have established regulatory frameworks of pharmacovigilance, although their system differ in organization and specific reporting requirements India through CDSSCO and pharmacovigilance programme of India [PvPI] has developed a broad ADR monitoring network and strengthened its regulatory requirements for MAHs

New Zealand, through Medsafe and the Centre For Adverse Reaction Reporting signal detection and safety communication. Both countries can further strengthen pharmacovigilance by improving by awareness among healthcare professionals, encouraging patient participation, enhancing electronics reporting system,

promoting timely and complete ICSR reporting and increasing the use of real world data and advanced analytical technologies. Greater collaboration and harmonization between national and international regulatory agencies can also improve the early detection and prevention of medicine related risks.^[10,13,14,15]

ACKNOWLEDGEMENT

The authors thank the Department of Regulatory affairs. Sree Siddaganga college of Pharmacy Tumakuru, and Dr. P. Ashok Kumar for guidance and supervision of the underlying project work from which this article is derived. This work received no specific grant from any funding agency in public, commercial, or not-for-profit sectors, and the authors declare no conflicts of interest.

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