Advanced Nursing & Patient Care International Journal
ISSN: 2642-0147

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Editorial *Volume 7 Issue 1*

Reflections on the Performance of the Pharmacovigilance Programme of India for the Year 2022-2023

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Received Date: October 18, 2024; **Published Date:** November 08, 2024

Abbreviations

PvPI: Pharmacovigilance Programme of India; IPC: Indian Pharmacopoeia Commission; ADRs: Adverse Drug Reactions; MvPI: Materiovigilance Programme of India; SEARN: South-East Asia Regulatory Network; ADRMS: Adverse Drug Reaction Management System; ICSRs: Individual Case Safety Reports; MAHs: Marketing Authorization Holders; CDSCO: Central Drugs Standard Control Organisation; MDAE: Medical Device Adverse Event

The performance report of the Pharmacovigilance Programme of India (PvPI) for the year 2022-2023 underscores the nation's assiduous commitment to patient safety through comprehensive drug and medical device safety monitoring [1]. Managed by the Indian Pharmacopoeia Commission (IPC), an autonomous institution under the Ministry of Health and Family Welfare, Government of India, the PvPI is instrumental in monitoring adverse drug reactions (ADRs), ensuring that the benefits of medications outweigh the associated risks. This report highlights not only the continued expansion of efforts in drug safety by the PvPI but also the growing importance of the Materiovigilance Programme of India (MvPI) in addressing medical device safety. These developments reflect the holistic approach to safeguarding public health by enhancing vigilance across pharmaceuticals and healthcare devices.

Strengthening National and Global Collaboration

The PvPI has been effective as a WHO Collaborating Centre, contributing to the global pharmacovigilance network, especially within the South-East Asia Regulatory Network (SEARN). Notably, the National Coordination Centre of PvPI at IPC has developed and integrated the adverse drug reaction management system (ADRMS), enhancing the seamless processing of individual case safety reports (ICSRs). This system, aligned with the drug dictionaries of the WHO, facilitates the real-time tracking of medication safety data.

Collaborations with the PvPI go beyond Indian borders, with regular exchanges of safety information, including newsletters and identified drug safety signals, with SEARN countries. This cross-border collaboration ensures that critical data related to the safe use of medications and vaccines reaches stakeholders across the region, fostering an environment of shared vigilance.

Expanding the Role of Adverse Drug Reaction Monitoring Centres

The backbone of the PvPI's success is the network of adverse drug reaction monitoring centres (AMCs) spread across India. In 2022-2023, the PvPI expanded this network, focusing on enrolling new AMCs in underserved states and regions. The AMCs play a pivotal role in collecting and analyzing ADRs, helping refine safety profiles of medications. Importantly, these centres are also evaluated rigorously on performance metrics to ensure the quality of their reporting.

Each AMC is not only a data collection point but a hub of training and skill development for healthcare professionals. This widespread network has contributed significantly to the more than 113000 ICSRs collected during the year, ensuring that every corner of the country is part of this crucial drug safety mechanism.

Training and Capacity Building for a Safe Healthcare System

A critical component of the PvPI is capacity building. During 2022-2023, the PvPI held numerous training programs, workshops, and advanced-level training sessions to educate healthcare professionals about pharmacovigilance practices. The goal was not limited to improve reporting rates but also to enhance the analytical capabilities of the workforce in assessing the benefits and risks of medications.

With over 100,000 stakeholders trained, these programs play a vital role in embedding pharmacovigilance practices within the healthcare system of India. By providing training on platforms such as VigiFlow, the PvPI ensures that healthcare professionals are equipped to manage and report adverse drug reactions effectively.

Contributions by Marketing Authorization Holders

The report highlights a significant rise in the number of ICSRs submitted by marketing authorization holders (MAHs). Following recent regulatory changes that made pharmacovigilance a legal obligation for MAHs, over 55,000 ICSRs were contributed by these entities during the reporting period. This initiative has encouraged drug manufacturers to become active participants in drug safety, fostering a more holistic approach to pharmacovigilance.

Public and Consumer Engagement in Pharmacovigilance

The PvPI has also made strides in engaging with the public, encouraging consumers to report suspected ADRs through a toll-free helpline and dedicated email channels. The National Toll-Free Helpline (1800-180-3024) has been critical in allowing patients to directly report ADRs. This consumer-driven approach has yielded numerous ICSRs from non-AMCs and direct consumer reporting channels. The push towards more inclusive reporting, where patients themselves play a role, marks a significant step toward patient-centred healthcare.

Medical Device Vigilance

In addition to ADR events, the 2022-2023 report highlights the growing importance of monitoring adverse events related to medical devices through the MvPI. Initially launched in 2015, the MvPI works closely with the Central Drugs Standard Control Organisation (CDSCO) to ensure that medical devices used across the country meet safety standards. During the 2022-2023 period, the MvPI recorded a substantial increase in medical device adverse event (MDAE) reports, with 6,441 MDAEs collected, marking a 65.5% increase compared to the previous year. This surge in reporting underscores the effectiveness of the MvPI and the heightened awareness of device safety among healthcare professionals.

The MvPI also forwarded 12 key recommendations to CDSCO based on MDAE data, advising regulatory action where necessary. For example, medical devices such as hip implants and stents were flagged for safety issues, which led to further investigations and regulatory scrutiny. This focus on devices as well as drugs represents a holistic approach to patient safety that incorporates all facets of medical treatment.

New Initiatives for Medical Device Reporting

A key milestone in the 2022-2023 period was the development of the MDAE reporting form in Hindi, an initiative aimed at increasing accessibility and encouraging more healthcare providers across India to report adverse events. The emphasis on regional language support is part of a broader strategy to localize reporting efforts and make it easier for healthcare workers at all levels to engage with the system. This initiative was paired with a series of awareness programmes and workshops aimed at both healthcare professionals and device manufacturers.

Vision for the Future

Looking towards the future, the PvPI is committed to advancing patient safety and promoting the rational use of medicines. Along with the MvPI, healthcare safety in India now covers both pharmaceuticals and devices, adding another layer of protection for patients. By continuously refining its strategies, expanding its network, and building capacity among healthcare professionals and consumers alike, the PvPI positions itself as a leader in pharmacovigilance, not only in India but also worldwide. Its commitment to fostering a safe healthcare system through vigilant monitoring and proactive reporting is a model that other nations may seek to emulate.

References

1. Pharmacovigilance Programme of India Performance Report 2022-2023. Indian Pharmacopoeia Commission: Ministry of Health and Family Welfare, Government of India. India, pp: 1-206.