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Research Article

Strengthening Pharmacovigilance Legislation in India: A Critical Review

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ABSTRACT

Pharmacovigilance (PV) is essential for monitoring and ensuring the safety of medicines after they are introduced to the market. In India, the Pharmacovigilance Programme of India (PvPI) has made commendable progress since its inception. However, significant challenges persist, including underreporting, limited enforcement mechanisms, and inadequate coverage of traditional medicines. This paper critically examines the legal and institutional framework for PV in India, compares it with international standards, and proposes reforms to enhance drug safety and public health. Emphasis is placed on strengthening mandatory reporting systems, expanding PV coverage, and using technology for better signal detection.

INTRODUCTION

Pharmacovigilance (PV) plays a vital role in public health by identifying, assessing, and preventing adverse drug reactions (ADRs). While India has emerged as a global pharmaceutical hub, the country has historically faced challenges in post-marketing drug surveillance. This paper explores the current state of PV legislation and infrastructure in India, highlighting key gaps and suggesting strategies to strengthen the system.

Historical Development of Pharmacovigilance in India:

India joined the WHO Programme for International Drug Monitoring in 1997. However, structured national pharmacovigilance activities began only in 2010 with the launch of the Pharmacovigilance Programme of India (PvPI), coordinated by the Indian Pharmacopoeia Commission (IPC) under the Central Drugs Standard Control Organization (CDSCO).

Key Regulatory Bodies

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- Central Drugs Standard Control Organization (CDSCO): India's national drug regulatory authority.
- Drugs Controller General of India (DCGI): Responsible for drug approval and safety oversight.
- Indian Pharmacopoeia Commission (IPC): Hosts the National Coordination Centre for PvPI.
- Ministry of Health and Family Welfare: Oversees policy formulation and health regulations.

Relevant Legislation and Guidelines

- Drugs and Cosmetics Act, 1940 and Rules, 1945: Establishes the legal foundation for drug regulation in India.
- Schedule Y: Outlines safety requirements during clinical trials.
- Rule 122 DAB: Mandates reporting of serious adverse events (SAEs) during trials.
- Good Pharmacovigilance Practices (GVP): Provides standard procedures for PV activities.
- PvPI Operational Guidelines: Define the structure and process for ADR reporting in India

5. Pharmacovigilance Programme of India (PvPI)

PvPI is India's flagship program for ADR monitoring. It coordinates over 450 Adverse Drug Reaction Monitoring Centres (AMCs) and utilizes digital platforms like Vigiflow for data entry. PvPI also supports tools like the ADR PvPI mobile app and online reporting portals to improve accessibility for healthcare professionals and patients.

Progress and Achievements PVPI'S key milestones include:

- Establishment of a nationwide AMC network.
- Increased ADR data submission to WHO's VigiBase.
- Development of user-friendly digital tools for reporting.
- Regular training programs for medical professionals.
- Despite these gains, data suggests ADR reporting remains low relative to the population and pharmaceutical output.

Challenges and Limitations

- Underreporting: Due to lack of awareness and fear of legal consequences.
- Limited Enforcement: No penalties for failing to report ADRs.
- Weak Industry Compliance: Pharmaceutical companies often underperform in mandatory reporting.
- No AYUSH Monitoring: Traditional systems like Ayurveda and Homeopathy are not included in PvPI.

Global Benchmarking

- European Union (EMA): Uses the EudraVigilance database and mandates detailed PV protocols.

- United States (FDA): Employs the MedWatch system and Risk Evaluation and Mitigation Strategies (REMS).

- Both agencies have strong legal frameworks and active enforcement. India can enhance its system by adapting aspects such as automated alerts, mandatory compliance, and transparent reporting practices.

Recommendations for Strengthening PV in India

- Make ADR reporting mandatory for healthcare professionals and pharmaceutical companies.

- Expand PV coverage to include AYUSH and over-the-counter (OTC) drugs.

- Introduce legal penalties for non-compliance.

- Adopt AI and big data tools for early signal detection and trend analysis.

- Promote PV awareness through medical education and public campaigns.

- Enhance collaborations with international regulatory bodies for knowledge sharing

CONCLUSION

India's pharmacovigilance landscape has matured significantly over the past decade. However, the system still lacks the robustness seen in developed nations. Addressing issues like underreporting, weak enforcement, and limited scope will be critical. With updated legislation, digital integration, and stakeholder training, India can build a world-class pharmacovigilance system that ensures medicine safety and protects public health

REFERENCES

1. CDSCO. (2023). Guidelines for Pharmacovigilance.
2. PvPI. (2022). Annual Performance Report.
3. WHO-UMC. (2023). Safety Monitoring of Medicinal Products.
4. Drugs and Cosmetics Act, 1940.
5. EMA and FDA official websites.
6. Indian Journal of Pharmacology (2023).

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