



EDITORIAL

Pharmacovigilance in India: Present and Future Prospects

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Dear Colleagues,

Pharmacovigilance is defined as the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or other important issues caused by drugs. Pharmacovigilance is a crucial element for clinical trials and drug development. It is majorly concern about the detection of Adverse Drug Reaction (ADR). ADRs are defined as “an unpleasant and unintended response to drugs that occurs at levels normally used for disease prevention, diagnosis and therapy or for the alteration of physiological function”. The Pharmacovigilance activity in India is regulated by the Indian Pharmacopoeia Commission (IPC) and the National Coordination Committee (NCC) through the Central Drug Standard Control Organisation (CDSCO). National Pharmacovigilance Program (NPvP) was inaugurated in November 2004 by the CDSCO of India's Ministry of Health and Family Welfare. The programme was suspended in 2009.

Recognizing the need for improved ADR monitoring in the country, the Indian government planned and launched revised ADR monitoring programme named as Pharmacovigilance Programme of India (PvPI) on 14th July, 2010 to establish a potential pharmacovigilance system in India with the National Coordination Center (NCC) at All India Institute of Medical Sciences (AIIMS) in New Delhi, which was later transferred to the Indian Pharmacopoeia Commission in Ghaziabad, India, in April 2011 to monitor adverse drug reactions in the country and protect public health.

Under PvPI, Adverse Drug Reaction Monitoring Centres (AMC) plays a vital role in collection and follow-up

of ADR reports from healthcare professionals. At present there are 395 AMCs under this programme, with the aim of gathering information on ADR from hospitals. The purpose of this programme is to collect, collate and analyze the reported data to arrive at an inference to recommend regulatory interventions for safeguarding the health of Indian population by ensuring that benefit outweighs the risks associated with the use of medicines. NCC-PvPI has identified and issued 124 drug safety alerts, 57 Prescribing Information Leaflet (PIL) changes including 7 signals for sensitization of stakeholders. NCC is continuously communicating the findings of PvPI to CDSCO for regulatory actions. PvPI programme in India is growing well, and India is the 9th largest contributor of ADR data to WHO database.

The pharmaceutical industry in India was valued at an estimated US\$42 billion in 2021. India is the world's largest provider of generic medicines by volume, with a 20% share of total global pharmaceutical exports. It is also the largest vaccine supplier in the world by volume, accounting for more than 50% of all vaccines manufactured in the world. In recent years, clinical trials and related activities increased immensely in India, hence it becomes necessary to understand the importance of Pharmacovigilance and its effect on product lifecycle. India is the most desired location for the growth of Pharmacovigilance industry because of the extensive availability of skilled and well-trained healthcare professionals. Indian pharmaceutical companies have improved their ability to develop and commercialise new products, highlighting the importance of establishing acceptable internal pharmacovigilance standards to detect

adverse drug events. The Drugs Technical Advisory Board (DTAB) had previously proposed that pharmaceutical companies be required to report adverse effects of marketed drugs. In spite of proactive nature of the recommendations, the mandate legislation was established in March 2016. Therefore, majority of pharmaceutical companies accepted ADR as an industrial practice; create a periodic communication and interactive section between PvPI and its stakeholders which results in progressive reporting in ADR reports. Pharmaceutical industry's ADR reporting rate to PvPI in 2015 was 18.80%. Over the past few years, many well-known pharmaceutical companies like Novartis, Wockhardt, Sun Pharma, Astrazenca, Pfizer etc., established either their independent Pharmacovigilance centres or getting associated with Pharmacovigilance service providers, thus generating new employment prospects. The growth of Pharmacovigilance would be subjected to automation, artificial intelligence and robotics. This era of digitalization has completely transformed and up marketed many business models including Pharmacovigilance.

NCC has mandated the Regional Training Centers (RTCs) to organize advance level training for the personnel's

of all AMCs under their respective regions and one continuing medical education (CME) in Pharmacovigilance at an AMC under their region to increase the awareness of healthcare professionals about the ADR reporting. In near future, all Medical Council of India approved institutions will be enrolled under the PvPI. Several tools and methods have been introduced by the PvPI including Suspected ADR Reporting form (For Healthcare Professionals), Medicines Side Effect Reporting form (For consumers) in Hindi, English and other vernacular languages, Mobile App (ADR PvPI), PvPI Helpline (Toll-free 1800 180 3024), etc. NCC-PvPI organizes regular training programmes including skill development programmes on Pharmacovigilance to enhance knowledge, skills and practice of stakeholder's and to promote quality and safety of medicines manufactured and marketed in India. Therefore, effective implementation of Pharmacovigilance in healthcare facilities will provide a dynamic and stable system to monitor the ADR reporting mechanism about safety of the drugs used in the country. This will reduce our dependence on western world data for taking regulatory decisions on drug safety on account of evolution of evidence based drug safety mechanism.

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