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Present Circumstances and Prospects of the Indian Pharmacovigilance Program

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Abstract

Any undesirable and unexpected response to a medication that occurs at levels usually employed in man for prevention, diagnosis, or therapy of illness, or for the change of physiological function, is referred to as an adverse drug reaction (ADR). We would be able to identify and target particular areas for robust pharmacological treatment if we had a better grasp of the frequency and type of ADRs, as well as patient opinions on quality of life. Because ADRs are life-threatening, it is critical to understand the common medicines that cause them, their therapeutic class, demographic data on patients who have experienced ADRs, and the medications they are taking concurrently. ADR-specific data, such as the type of reaction, the system impacted, and the likely reasons, will also be very useful in reducing ADRs. To maintain track of newly launched medicines and medical goods, the procedure of identifying and concluding regarding ADRs should be constant and continuing. Furthermore, if possible, strict pharmacological analysis, clinical data, and an in vivo investigation are also necessary. The focus of this article is on the unfavourable response and the techniques for assessing it.

Keywords: *Pharmacovigilance program, Adverse drug reaction, Vigflow system, Medications*

INTRODUCTION

The issue of medication safety is now a top focus. The 1960s thalidomide disaster awakened the attention of drug regulators and other concerned groups to the need to create a method to assure medication safety; earlier, the concerns were shrouded in mystery. Drug safety concerns were globalised, strengthened, and systematised after the World Health Organization (WHO) launched the Programme for International Drug Monitoring in 1968. In 2010, India established the Pharmacovigilance Program of India (PvPi), years after the programme began. This program's major goal is to provide advanced patient care and safety in connection to the use of pharmaceuticals, ensuring logical and effective treatment while protecting public health. [1]

Pharmacovigilance (abbreviated PV or PhV) is a term that refers to the monitoring of pharmaceuticals. The etymological roots are pharmakon (Greek) and vigilare (Latin), which mean "to stay awake or attentive, to keep watch." is the monitoring of pharmaceuticals with the goal of discovering new knowledge regarding product risks and preventing patient damage. ADR, on the other hand, is an unpleasant and unexpected reaction to a medication that occurs at dosages typically employed for disease prevention, diagnosis, or therapy, or for the change of physiological function.[2] ADRs are a prevalent clinical concern that must be minimised in order to lessen the country's economic burden.

INDIAN SCENARIO

In 1986, a formal ADR monitoring system consisting of 12 regional centres, each covering a population of 50 million, was suggested for India, and this was the beginning of pharmacovigilance in India. [3]

However, nothing significant transpired until India joined the WHO ADR Monitoring Program in Uppsala, Sweden, a decade later in 1997. As a result of the failure of this endeavour, the WHO-sponsored and World Bank-funded National Pharmacovigilance Program for India was launched on January 1, 2005. 4 The Government of India launched the Pharmacovigilance Programme of India (PvPI) in July 2010 with AIIMS, New Delhi as the National Coordinating Center (NCC) for monitoring adverse drug reactions (ADRs) across the country in order to protect public health by ensuring the safety of medical goods.

On April 15, 2011, the NCC was relocated from AIIMS, New Delhi, to IPC, Ghaziabad. Prior to the registration and marketing of a pharmaceutical in the nation, its safety and efficacy are largely assessed through the use of the drug in clinical studies. These trials also detect adverse responses, but some of the more serious ones, such as those that take a long time to manifest or occur infrequently, may go undetected in clinical trials. Furthermore, the controlled settings under which drugs are tested in clinical trials may not always mirror how they would be used in practise. To be deemed safe, a medicine's predicted benefits must outweigh any potential for negative side effects. As a result, a continual post-marketing monitoring system is required to get a full safety profile of medical goods. In addition to conveying hazards to healthcare professionals and the general public, PvPI provides a mechanism to collect data and utilise inferences to suggest regulatory measures.

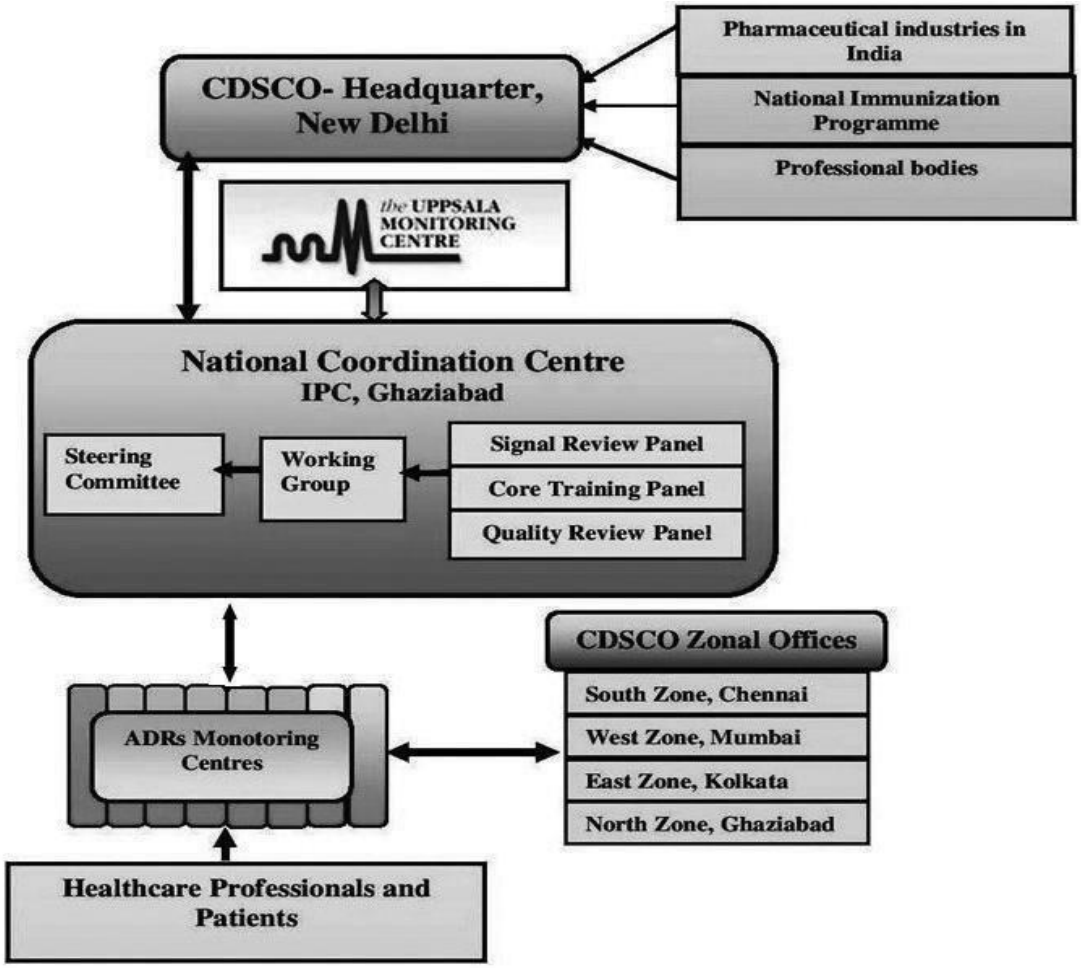

Figure 1 Communicational organization of pharmacovigilance program of India (PvPI).

Medical colleges and hospitals have become the PvPI's cornerstone in recent years. They serve as Adverse Drug Monitoring Centers (AMCs), which are in charge of collecting Individual Case Safety Reports (ICSRs) and following up to acquire any further comprehensive information needed for scientific evaluation of the cases. 5 Until August 2015, 150 ADR Monitoring centres (both government and non-government) have been created under PvPI. Other special centres, such as 20 ART (Anti-Retroviral Therapy) and 17 RNTCP (Revised National Tuberculosis Program) centres, have also been recognised for reporting adverse occurrences spontaneously. 6

The Institute of Medical Sciences (IMS) at Banaras Hindu University (BHU) in Varanasi is one of the PvPI's approved ADR Monitoring Centers (AMCs) under the Ministry of Health and Family Welfare. The PvPI unit at IMS-BHU consists of a coordinator from the Department of Pharmacology, one member (Assistant Professor level) from several clinical departments, and one Technical Associate delegated by the National Coordination Centre (NCC-PvPI). The technical associate is in charge of collecting ICSRs (individual case safety reports) and following up on them. All of the ADR reports that had been examined and signed were entered into the VigiFlow system (online software). All government and private primary health centres (PHCs) and community health centres (CHCs) can submit ADR reports to this facility, which also serves as a Regional Pharmacovigilance Centre.

There is a widespread belief among the general public that natural implies safe, and that natural treatments are non-toxic and free of adverse effects. However, according to the "Charka Samheta," a famous Ayurvedic text, ADR happens when herbal medications are administered or made incorrectly. 7 To provide adequate pharmacovigilance for Ayurveda, Siddha, and Unani (ASU) medications in India, the Department of AYUSH established the National Pharmacovigilance Centre for ASU drugs, which is critical for centrally monitoring the programme. According to WHO recommendations, the majority of ADRs associated with herbs and herbal products are due to poor quality or inappropriate use. In the country, there are a variety of herbal, mineral, metallic, animal, and other types of medications. 8 There are about 6,000 licenced medication producers and over 60,000 branded formulations in India, which is a huge nation with a lot of medicine brands.

India is one of the world's major producers of medicines and is quickly becoming a centre for clinical trials. Because many new medications are being launched in India, there is a pressing need to enhance the pharmacovigilance system in order to safeguard the Indian people from possible harm caused by new or previously used drugs.[9] National Drug Policy is a significant area where pharmacovigilance is used. Most nations moved forward to create drug regulatory organisations with specialised pharmacovigilance programmes to monitor and analyse ADR and disseminate results to key stakeholders in order to guarantee the safety and reasonable use of the medication.[10] Pharmacovigilance is a young and tiny science that plays an important role. It is a well-established academic speciality in which current curriculum in professional training programmes such as clinical medicine, clinical pharmacy, clinical pharmacology, and medical biology address all aspects of pharmacovigilance. [11]

Any medication has the potential to have adverse effects. However, it was primarily seen in the antibiotics and anticancer agents classes of medicines, which accounted for 16 percent and 15% of all ADR instances, respectively. [12] Because ADRs are becoming increasingly problematic, a signal has been included. It's a proven and prospective indication of new ADR. Any new probable causal relationship between a suspected ADR and medication that was previously unknown or incompletely described is referred to as a signal. [13] Many Indian firms have been investing in research and development in recent years to improve their ability to create and commercialise new drugs using their own research efforts. Due to its big population, high participation rate, and low cost, India is eventually becoming a new centre for clinical research operations. Pharmacovigilance is a strong system that protects patients from damage by detecting previously unknown medication hazards, explaining predisposing variables, and assessing risk in proportion to benefits. [14]

CONCLUSION

Pharmacovigilance is a well-established mechanism that ensures the safety of pharmaceutical products. It lowers the rate of ADRs while also assisting in the reduction of the country's fiscal burden by protecting public health. PvPI is one of the necessary actions done by the Government of India's Ministry of Health and Family Welfare to ensure the safe and sensible use of medications. No medical medication is totally risk-free, and these drugs must be

continuously monitored to guarantee patient safety. The Indian Pharmacopoeia Commission serves as the national coordination hub for PvPI, with all of its stakeholders contributing significantly to the achievement of its goals and objectives.

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