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Pharmacovigilance Programme in India: Current Status and Its Perspectives

Dinesh Kumar, Muthu MS* and Pandey BL

Department of Pharmacology, Institute of Medical Sciences, Banaras Hindu University, Varanasi, India.

Editorial

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*For Correspondence

Muthu MS, Assistant Professor, Department of Pharmacology, Institute of Medical Sciences, Banaras Hindu University, Varanasi, India, Tel: + 91 9235195928; Fax: + 91 542 236 7568

E-mail: muthubits@rediffmail.com

INTRODUCTION

The safety concern of drug is now becoming the priority area. The thalidomide tragedy of 1960's opened the eyes of drug regulators as well as other concern body to establish a way to ensure drug safety, previously the issues was in shadow. The drug safety issues were globalised, strengthened and systematized after the establishment of World Health Organization (WHO) Programme for International Drug Monitoring in 1968. Every drug is associated with beneficial as well as undesirable or adverse effect. Adverse drug reactions (ADR) are the common clinical problem. The hospitalization due to ADR in some countries is about or more than 10%. In addition, it is estimates that 10-20% of the hospital inpatient suffers from ADR. Appropriate and effective monitoring of ADR, i.e., pharmacovigilance, is the only best way to safeguard the public health^[1]. Pharmacovigilance (abbreviated PV or PhV The etymological roots are: *pharmakon* (Greek), "drug;" and *vigilare* (Latin), "to keep awake or alert, to keep watch.") is the pharmacological science relating to the detection, assessment, understanding and prevention of adverse effects, particularly long term and short term side effects of the medicines. A response to a drug which is noxious and unintended, and which occurs at doses normally used for the prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function^[2].

INDIAN SCENARIO

The origin of pharmacovigilance in India goes back to 1986, when a formal ADR monitoring system consisting of 12 regional centers, each covering a population of 50 million, was proposed for India^[3]. However, nothing much happened until a decade later when in 1997, India joined the WHO ADR Monitoring Programme based in Uppsala, Sweden. This attempt was unsuccessful and hence, from 1 January 2005, the WHO-sponsored and World Bank-funded National Pharmacovigilance Program for India was made operational^[4]. The Pharmacovigilance Programme of India (PvPI) was initiated by the Government of India in July 2010 with AIIMS, New Delhi as NCC for monitoring ADR in the country for safe-guarding public health by assuring the safety of medicinal products. The NCC was shifted from AIIMS, New Delhi to IPC, Ghaziabad on 15th April 2011. Before registration and marketing of medicine in the country, its safety and efficacy experience is based primarily on the use of the medicine in clinical trials. These trials also detect adverse reactions but some of the important reactions, such as those, which take a long time to develop, or those, which occur rarely, may not be detected in the clinical trials. In addition, the controlled conditions under which medicines are used in clinical trials do not necessarily reflect the way they will be used in practice. For a medicine to be considered safe, its expected benefits should be greater than any associated risks of harmful reactions. So in order to gain a comprehensive safety profile of medicinal products, a continuous post-marketing monitoring system is essential. PvPI provides such a system to collate the data and use the inferences to recommend regulatory interventions, besides communicating risks to healthcare professionals and the public (Figure 1). The Medical Colleges and hospitals are the corner stone of the PvPI. They act as AMCs which are responsible for collecting the Individual Case Safety Reports (ICSRs) and performing the follow up to obtain necessary supplementary detailed information for scientific evaluation of the cases^[5].

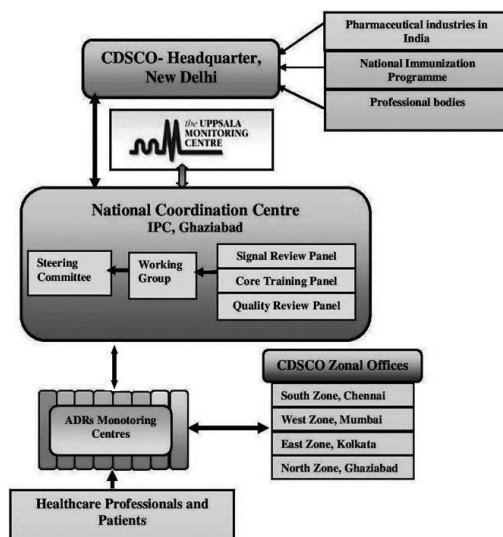


Figure 1. Communicational organization of pharmacovigilance program of india (PvPI).

Currently, 150 ADR Monitoring centers (including government and Nongovernment) are established under PvPI till august 2015. Other Special centers like 20 ART (Anti-Retroviral Therapy) and 17 RNTCP (Revised National Tuberculosis Program) centers also recognized for spontaneous reporting of adverse events [6]. Our Institute, i.e., Institute of Medical Sciences (IMS), Banaras Hindu University (BHU), Varanasi, is one of the recognized ADR Monitoring centre (AMC) of PvPI, Under Ministry of Health and Family welfare, Government of India. The PvPI unit of IMS-BHU constituted by Head of the Department of Pharmacology as coordinator, one member (Assistant Professor level) of various clinical departments and one Technical Associate deputed by National coordination Centre (NCC-PvPI). The technical Associate is responsible for collecting ICSRs (individual case safety report) and ensuring proper follow up. All the scrutinized and signed ADR reports were entered into VigiFlow (online software). This centre is also works as Regional Pharmacovigilance Centre where all government and private primary health centers (PHCs) and community health centers (CHCs) can submit their ADR reports. There is popular misconception that natural means safe and remedies of natural origin are harmless and are devoid of ADR. "Charka Samheta", classical book of Ayurveda describes ADR occurs when herbal medicines are used or prepared inappropriately [7]. To put pharmacovigilance for Ayurveda (ASU) drugs in proper place in India, formation of a National Pharmacovigilance Centre for ASU drugs under the control of Department of AYUSH is highly essential which would monitor the program centrally. This program aims to provide ADR data as per WHO guidelines, most of the ADR linked with herbs and herbal products are because of poor quality or improper usage. Various drugs of herbal, mineral, metallic, animal and other origin available in the country [8]. India is a vast country and there is a surfeit of drug brands-more than 6,000 licensed drug manufacturers and over 60,000 branded formulations. India is the fourth largest producer of pharmaceuticals in the world and is also emerging as a hub for clinical trials. Many new drugs are being introduced in the country, so there is an immense need to improve the pharmacovigilance system to protect the Indian population from potential harm that may be caused by some of the new drugs [9]. Pharmacovigilance is ingrained, and highly so, in several areas of healthcare management of general population. The key area where pharmacovigilance incorporated is National Drug Policy. For most nations, the first step to ensure safe and rational use of medicine is the establishment of drug regulatory bodies with dedicated pharmacovigilance program to monitor and assess the ADR and communicate findings to relevant stakeholders [10]. Pharmacovigilance is relatively new and small science. It is not a well-established academic specialism. Current curricula in training programs of professions such as clinical medicines, clinical pharmacy, clinical pharmacology or medical biology do not cover all the skills needed in pharmacovigilance [11]. ADR were possible with any class of drugs. However, antibiotics and antitumor agents are the most troublesome classes of drugs which are responsible in causing 16% and 15% of all cases of ADR [12]. Signal is a potential and established indicator of new ADR. Signal is referred as any new possible causal link between a suspected ADR and drug, which is previously unknown or incompletely documented [13]. In recent years, many Indian companies are increasing the investment in research and development and are enhancing their capacity to develop and market new drug with their own research efforts. Further, India is becoming a hub for clinical research activities due to its large population, high enrollment rate, and low cost. Moreover, the lag period when a drug is placed for the first time on the market in USA, Europe, Japan or somewhere else in the world, and its subsequent availability in India has decreased considerably. As a result, for such drugs the long term safety data is not available and the time of their marketing in India [14]. Pharmacovigilance protect the patients from unnecessary harm by identifying previously unrecognized drug hazard, elucidating pre-disposing factors and quantifying risk in relation to benefits [15].

CONCLUSION

Pharmacovigilance is the only best tool to ensure the safety of drug product. Every drug is associated with beneficial as well as undesirable or adverse effect. ADR are the common clinical problem which requires minimization to reduce economic burden of our country. In this context launch of Pharmacovigilance program of India (PvPI) marks an important milestone in country's

march towards safeguarding public health. PvPI is one of the indispensable steps taken by Ministry of Health and Family Welfare, Government of India for ensuring safe and rational use of medicines. No medicinal product is completely devoid of risk and a continuous monitoring of these products is required to ensure patient safety. Indian Pharmacopoeia Commission as National Coordination centre for PvPI with all their stakeholders performing remarkably in achieving its mission and objectives.

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