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MINI REVIEW ARTICLE

REVIEW ON PHARMACOVIGILANCE PRACTICES IN INDIA

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ABSTRACT:
In India, pharmacovigilance practices have been gradually evolving over the past decade in order to better monitor drug safety metrics. The traditional system of spontaneously reporting adverse drug reactions (ADRs) to regulatory authorities is no longer feasible, given the large number of drugs and patients in India. There is still a need for better coordination between different stakeholders, and for more resources to be allocated to such activities. This article looks at some of the most recent developments in this area, as well as their implications for patient outcomes. The Pharmacovigilance Programme of India (PvPI) was established in 2010 and is managed by the Central Drug Standard Control Organization (CDSCO). The PvPI monitors the safety of medicines that are marketed in India, with the aim of protecting patients from adverse effects. It collects data on adverse events through a reporting system accessible to both health care professionals and members of the public. The National Pharmacovigilance Monitoring Centre (NADRMC) in India monitors adverse drug reactions (ADRs) from all over the country. The centre collects data from various sources such as hospitals, clinics, voluntary reporting by patients/caregivers and health care professionals. This will help reduce healthcare costs as well as protect patient safety by minimizing risk of harm associated with inappropriate use of drugs.

Key words: *Pharmacovigilance, PvPI, Central Drug Standard Control Organization, NADRMC*

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INTRODUCTION:

Medical care and pharmaceuticals are two of the most important resources in any given country, but with these comes the potential for significant harm. To ensure that citizens of a particular country receive safe medical treatment, it is essential to have systems in place for monitoring drug safety and efficacy. Pharmacovigilance is one such system which monitors adverse events associated with drugs or medical devices from production to consumption by the public [1]. In India, pharmacovigilance practices have been gradually evolving over the past decade in order to better monitor drug safety metrics. This article looks at some of the recent developments in pharmacovigilance practices in India and their implications for patient outcomes.

THE CURRENT STATE OF PHARMACOVIGILANCE IN INDIA:

The current state of pharmacovigilance in India is in a state of flux. The traditional system of

spontaneously reporting adverse drug reactions (ADRs) to the regulatory authorities is no longer feasible, given the large number of drugs and patients in India. The need for a more systematic approach to pharmacovigilance has been recognized by the Indian government and various other stakeholders [2].

A national pharmacovigilance program was launched in 2010, with the goal of establishing a centralized database of ADRs. However, this program has faced several challenges, including a lack of awareness among healthcare professionals and patients, and a lack of funding. As a result, the program has not been able to meet its targets.

In addition to the national program, there are also several initiatives at the state level aimed at improving pharmacovigilance practices in India. These include programs to train healthcare professionals on how to report ADRs, and campaigns to raise awareness among patients about the importance of reporting ADRs [3].

Despite these efforts, the current state of pharmacovigilance in India remains far from ideal. There is still a need for better coordination between different stakeholders, and for more resources to be allocated to pharmacovigilance activities.

THE ROLE OF THE CENTRAL DRUGS STANDARD CONTROL ORGANIZATION:

The Central Drugs Standard Control Organization (CDSCO) is the national regulatory body for pharmaceuticals and medical devices in India. The organization is responsible for ensuring the safety, efficacy, and quality of all drugs and medical devices sold in the country. CDSCO also regulates clinical trials and marketing of drugs and medical devices [4].

Pharmacovigilance practices in India are designed to monitor and report adverse events associated with use of pharmaceutical products. These practices are important in ensuring public safety and protecting the interests of patients. CDSCO is responsible for coordinating pharmacovigilance activities across different stakeholders, including government agencies, health care professionals, industry, and academia.

THE PHARMACOVIGILANCE PROGRAMME OF INDIA:

The Pharmacovigilance Programme of India (PvPI) was established in 2010 and is currently managed by the Central Drug Standard Control Organisation (CDSCO). The programme monitors the safety of medicines that are marketed in India, with the aim of protecting patients from adverse effects [5].

The PvPI collects data on adverse events associated with medicines through a reporting system that is accessible to both health care professionals and members of the public. Reports can be submitted online, by mail, or through a toll-free number. The PvPI also encourages patients and their caregivers to report any adverse events that they may have experienced [4].

The data collected by the PvPI is used to identify potential safety concerns and to monitor the safety of medicines marketed in India. The PvPI also conducts risk management activities, such as issuing alerts about potential safety concerns and working with companies to improve the safety profiles of their products [3].

The Pharmacovigilance Programme of India is an important part of ensuring the safety of medicines in India. By collecting data on adverse events and conducting risk management activities, the PvPI helps to protect patients from harmful effects of medicines [2].

THE NATIONAL ADVERSE DRUG REACTION MONITORING CENTRE:

The National Adverse Drug Reaction Monitoring Centre (NADRMC) was established in 2004 by the Ministry of Health and Family

Welfare, Government of India. It is a national pharmacovigilance program which monitors adverse drug reactions (ADRs) from all over the country [1,2].

NADRMC has a well-defined mechanism for reporting, recording and monitoring ADRs. The centre collects data from various sources such as hospitals, clinics, voluntary reporting by patients/caregivers and health care professionals. The collected data is analysed and processed to generate reports which are shared with relevant stakeholders [3].

NADRMC also provides training on pharmacovigilance to health care professionals and students. In addition, the centre organises workshops and conferences on pharmacovigilance to create awareness about the importance of this program [2,3].

OTHER INITIATIVES BY THE GOVERNMENT OF INDIA:

The Government of India has taken several initiatives to ensure the safety and efficacy of medicines in the country [3,4,5]. These include:

1. Establishing a Central Drugs Standard Control Organization (CDSCO) to regulate the quality of medicines
2. Formulating a National Pharmacovigilance Programme to track adverse events associated with medicines.
3. Setting up an Expert Committee on Clinical Trials to streamline the process of clinical trials in India
4. Creating a National Registry of Clinical Trials to promote transparency and accountability in clinical trials conducted in India

CONCLUSION:

In conclusion, pharmacovigilance practices in India are gradually improving with more awareness and initiatives from the government. The public must be educated on the importance of reporting adverse drug reactions to collection sites and monitoring authorities. By utilizing an effective surveillance system like PVNet we can ensure that any unexpected or harmful reactions to medications can be identified quickly, and appropriate action taken promptly. This will help reduce healthcare costs as well as protect patient safety by minimizing risk of harm associated with inappropriate use of drugs.

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