Pharmacovigilance
Pharmacovigilance Programme in India

[1]Umesh I. Kale, [2]Rutvik R. Kadambande, [3]Rohit B. Lamkane

[4]Rushikesh S. Harihar, [5]Prof.T.A.Mandhre
[1]Navsahydri Institute of Pharmacy, Pune, Maharashtra India

ABSTRACT: Pharmacovigilance is the detection, assessment, understanding and prevention of adverse effects of medicines. Under-reporting of adverse drug reactions (ADRs) is a major problem worldwide. PV is an integral part of clinical research and is a key part of drug safety. India has a formal adverse drug reaction monitoring system. The programme, now known as the Pharmacovigilance Programme of India (PVPI), was launched on July 14, 2010 by the Government of India, with the AIIMS in New Delhi serving as the National Coordination Centre (NCC) for monitoring ADRs in the country and protecting public health. This programme established 22 ADR monitoring centres, including AIIMS in New Delhi, in 2010.On April 15, 2011, the NCC was transferred from the AIIMS in New Delhi to the Indian Pharmacopoeia Commission (IPC) in Ghaziabad, Uttar Pradesh, to ensure more effective programme implementation. The primary goal of the NCC at IPC is to generate independent data on the safety of medicines that is comparable to global drug safety monitoring standards.

KEYWORDS: The Indian Pharmacovigilance Story, Importance of Pharmacovigilance, Role of Pharmacovigilance in Medicines Regulation, Drugs and Adverse drug reaction.

I. INTRODUCTION

Pharmacovigilance (PV), also known as drug safety, is the pharmacological science relating to the detection, assessment, understanding and prevention of adverse effects, particularly long term, and short term side effects of medicines. PV is an important and integral part of clinical research. The under-reporting of adverse drug reactions (ADRs) is the major setback worldwide which may be attributed to the lack of time and report forms. It has been known that the world health organization (WHO) has initiated the program of reporting all adverse reactions possessed by the drugs. Moreover, its concerns have been widened to include the herbal drug products, traditional and complementary medicines, blood products, biologicals, medical devices, and vaccine. Furthermore, PV plays a variety of roles, including the identification, quantification, and documentation of drug-related problems that cause drug-related injuries. Furthermore, national PV programs have been implemented, which play an important role in raising public awareness about drug safety. This review article discusses the need for and significance of PV in the daily lives of doctors, patients, and the pharmaceutical industry. [1]

Pharmacovigilance is an essential component of clinical research. Throughout the product life cycle, both clinical trial safety and post-marketing pharmacovigilance (also known as post marketing studies or Phase IV clinical trials) are critical. With a relatively high number of high-profile drug withdrawals recently, both the pharmaceutical industry and various regulatory agencies around the world have raised the standard. Major pharmaceutical companies have now adopted early detection of signals from post marketing surveillance studies and early phase clinical trials in order to identify the risks associated with their medicinal product/s as early as possible. If such a risk exists, it must be effectively managed by implementing robust risk management plans throughout the product's life cycle. Risk Minimization Programs/Strategies are another name for these risk management plans. [2]

II. THE INDIAN PHARMACOVIGILANCE STORY

It wasn't until 1986 t0hat India was proposed a formal adverse drug reaction (ADR) monitoring system comprised of 12 regional Centre's, each covering a population of 50 million, 2 India collaborated with the World Health Organization (WHO) Adverse Drug Reaction Monitoring Programme in Uppsala, Sweden, in 1997. Three ADR monitoring centers were identified, all of which are located in teaching hospitals: a National Pharmacovigilance Centre in the Department of Pharmacology at the All India Institute of Medical Sciences (AIIMS) in New Delhi, and two WHO special centres in Mumbai (KEM Hospital) and Aligarh (JLN Hospital, Aligarh Muslim University). These centres were supposed to report ADRs to India's drug regulatory authority. The primary function of these centres was to track adverse drug reactions (ADRs) to medicines sold in India. They hardly functioned, however, because information about the need to report ADRs and the functions of these monitoring centres had yet to reach prescribers, and there was a lack of government funding. This attempt was unsuccessful, so the WHO-sponsored and World Bank-funded National Pharmacovigilance Program for India became operational on January 1, 2005. 3 The Indian National Pharmacovigilance Program is now operational. [3]

III. IMPORTANCE OF PHARMACOVIGILANCE

It is the science that deals with the complex process of understanding and explaining the nature of ADR in a patient who is taking either oral, parenteral, or intravenous (I.V) drugs for a medical condition. The drugs that are currently on the market around the world have been subjected to a battery of tests as well as clinical trials in animals and human subjects in order to determine the drug's safety for a specific disease and the exact side effects associated with it. Even so, a large portion of it goes undetected, and some ADR are discovered during post-marketing surveillance. It is estimated that there are a significant number of ADRs, which reduce the quality of life, lengthen hospitalisation stays, and increase mortality. A landmark study published in 1998 by Lazarou

described ADRs as the fourth to sixth leading cause of death in the United States, with ADRs accounting for 3-7% of all hospital admissions.[4]

IV. AIMS OF PHARMACOVIGILANCE

The thalidomide tragedy emphasises the critical importance of effective drug monitoring systems for all medicines. The primary goals of pharmacovigilance programmers are to improve patient care and safety in relation to the use of medicines, as well as all medical and paramedical interventions, to improve public health and safety in relation to the use of medicines, to contribute to the assessment of benefit, harm, effectiveness, and risk of medicines, and to encourage the safe, effective use of medicines. Promote rational and more effective (including cost-effective) use, education, and clinical training in pharmacovigilance, as well as effective communication to health professionals and the general public.[5]

V. ADR (ADVERSE DRUG REACTION)

An adverse drug reaction (ADR) is defined as a fortuitous and harmful to a health product that causes at the doses occasionally or tested for the diagnosis, hindrance, or treatment of a disease or the alteration of AN organic function. Though it is difficult to identify the actuating agent associated with the adverse drug reactions (ADRs) encountered, the ingredients. The magnitude of risk, as well as the magnitude of expected medical specialty benefits, must be considered when deciding whether or not to use a specific drug in a given patient. Adverse drug reactions (ADRs) are classified into two types:

- predictable (Type-A) reactions
- Unpredictable (Type-B) reactions.

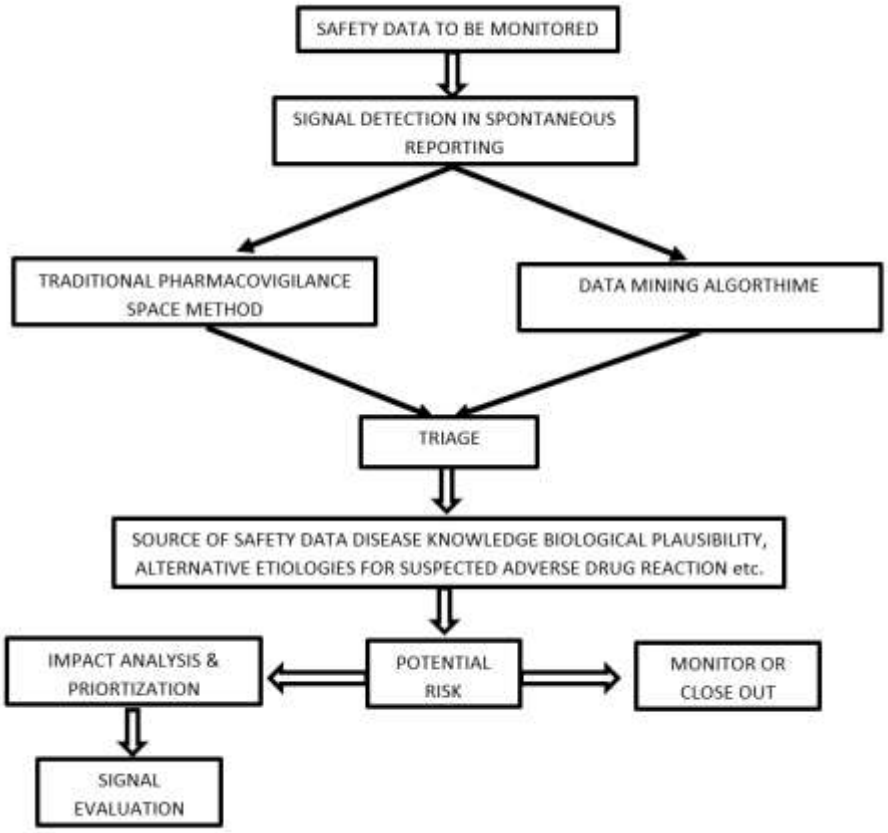
Type-A (predictable) Reaction: This square measure supported pharmacologic properties of the medicine such as increased but quantitative response to the drug that include side effects, Gynogenic effects, and drug withdrawal consequences.

Type-B (unpredictable) Reaction: This square measure supported patient characteristics rather than the drug's known actions; it includes allergic reaction and specialty. These are less common, usually not dose-related, and are usually quite serious and necessitate drug withdrawal. a list of some suspected and recognized medicines related to adverse effect .[6]

Drug	Adverse Drug Reactions (ADRs)
Thalidomide	Phocomelia, Multiple defects
Methotrexate	Multiple defects, Foetal death
Androgen	Virilization, limb, esophageal, cardiac defects
Progestins	Virilization of female foetus
Stilboestrol	Vaginal carcinoma in teenage female offspring
Tetracyclines	Discolored or deformed teeth, retarded bone growth
Warfarin	nose, eye and hand defects, growth retardation
Phenytoin	Various malformations
Lithium	Foetal goiter, cardiac and other abnormalities
Aspirin/ Indomethacin	Premature closer of ductus arteriosus

Table 1: known drugs and its adverse effect.

Signal Detection And Evaluation Steps: The evaluation steps for safety and prevention of ADR.



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VI. ROLE OF PHARMACOVIGILANCE IN MEDICINES REGULATION

Robust regulatory arrangements lay the groundwork for a national method of medicine safety and public trust in medicines. To be effective, drug regulatory authorities' remit must extend beyond the approval of new medicines to include a broader range of issues relating to medicine safety, including:

- clinical trials;
- the safety of complementary and traditional medicines, vaccines, and biological medicines;
- The development of lines of communication between all parties with an interest in medicine safety, ensuring that they can function efficiently and effectively.

Pharmacovigilance programmes and drug regulatory authorities must work together to achieve their respective goals. On the one hand, pharmacovigilance programmes must maintain strong links with drug regulatory authorities to ensure that the latter are well informed about safety issues in daily clinical practice, whether these issues are relevant to future regulatory action or to public concerns. On the other hand, regulators must comprehend the specialized and critical role that pharmacovigilance plays in ensuring the continued safety of pharmaceutical products. [7]

VII. PHARMACOVIGILANCE IN INDIA

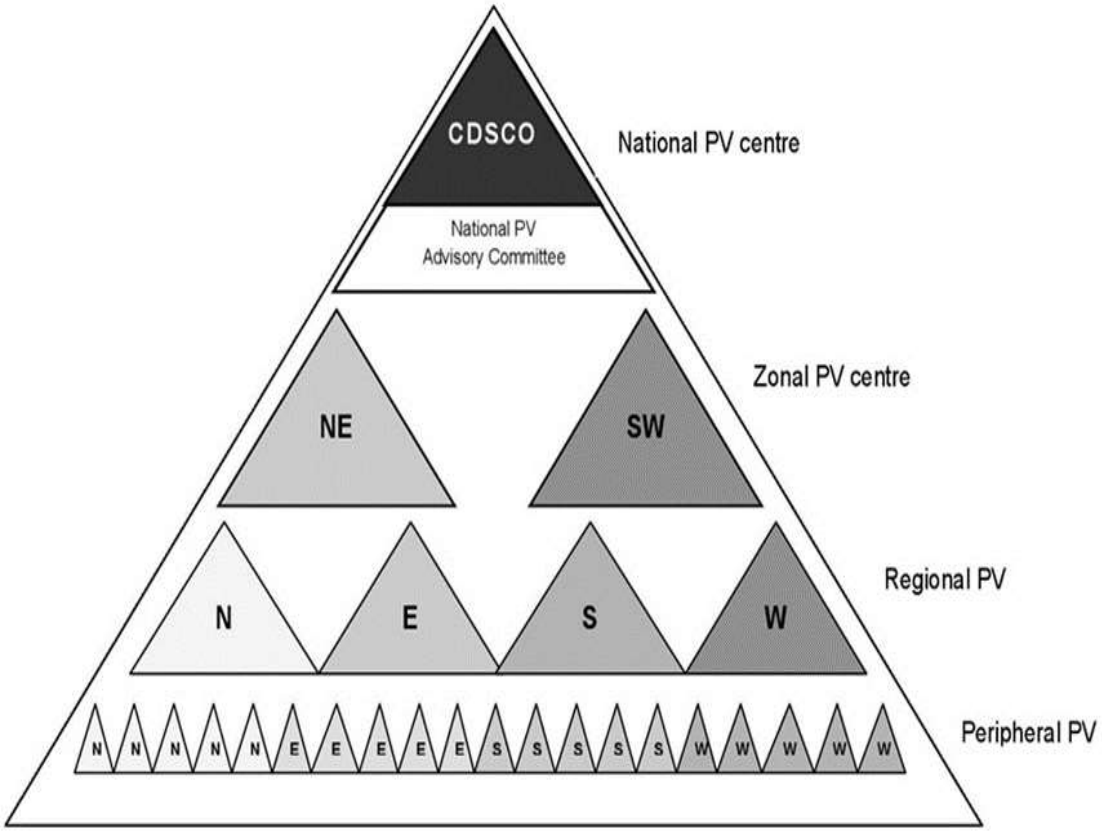
In India, consideration for ADR surveillance emerged relatively late, as there was previously no concept of medicine surveillance in the country. Despite the fact that PV is still in its infancy, it is not new to India. It wasn't until 1986 that a few physicians, mostly from academic institutions, called for more attention to be paid to the potential side effects of prescription medications and rational medication prescribing. This resulted in the establishment of the first ADR monitoring programme, which consisted of 12 regional centres, each covering a population of 50 million.

Nothing significant happened until 1997, when India joined the WHO Adverse Drug Reaction Monitoring Programme in Uppsala, Sweden. Three ADR monitoring centres were identified, all of which are located in teaching hospitals: a National Pharmacovigilance Center in the Department of Pharmacology at the All India Institute of Medical Sciences (AIIMS), New Delhi, and two WHO special centres in Mumbai (KEM Hospital) and Aligarh (JLN Hospital, Aligarh). These centres were supposed to report ADRs to India's drug regulatory authority. The primary function of these centres was to monitor ADRs to medicines sold in India. However, they were inoperable because information about the need to report ADRs and the functions of these monitoring centres never reached prescribers, and there was a lack of government funding. This attempt was unsuccessful, and thus, as of January 1, 2005, The WHO-sponsored and World Bank-funded National Pharmacovigilance Program (NPVP) for India was established. Depicts the structure of the NPVP.

The National Pharmacovigilance Advisory Committee, based at the Central Drugs Standard Control Organization, was to supervise the NPVP, which was established in January 2005. (CDSCO). The South-West (SW) zonal centre (located in the Department of Clinical Pharmacology, Seth GS Medical College and KEM Hospital, Mumbai) and the North-East (NE) zonal Centre (located in

the Department of Pharmacology, AIIMS, New Delhi) were to collect information from all over the country and send it to the committee as well as the Uppsala Monitoring Centre (UMC) in Sweden.

Three regional Centre's would report to the Mumbai Centre, while two would report to the New Delhi Centre. Each regional centre, in turn, would have several peripheral centres reporting to it (a total of 24). The programme had three broad goals. The program's short-term goal was to foster a reporting culture, the intermediate goal was to engage a large number of healthcare professionals in the system in information dissemination, and the long-term goal was for the programme to be a benchmark for global drug monitoring. This programme, however, also failed.[8]



National Pharmacovigilance Programme Zones in India

VIII. CURRENT PV PROGRAM IN INDIA

Recognizing the need to restart the NPVP, the Department of Pharmacology, AIIMS, and CDSCO collaborated in late 2009 to develop the framework for the new and current programme. The programme, now known as the Pharmacovigilance Programme of India (PVPI), was launched on July 14, 2010 by the Government of India, with the AIIMS in New Delhi serving as the National Coordination Centre (NCC) for monitoring ADRs in the country and protecting public health. This programme established 22 ADR monitoring centres, including AIIMS in New Delhi, in 2010. On April 15, 2011, the NCC was transferred from the AIIMS in New Delhi to the Indian Pharmacopoeia Commission (IPC) in Ghaziabad, Uttar Pradesh, to ensure more effective programme implementation. The primary goal of the NCC at IPC is to generate independent data on the safety of medicines that is comparable to global drug safety monitoring standards. Depicts the PVPI target phases year by year.

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