Volume 9, Issue 5, May – 2024 International Journal of Innovative Science and Research Technology
ISSN No:-2456-2165 https://doi.org/10.38124/ijisrt/IJISRT24MAY509

Materiovigilance: An Overview

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Abstract:- Pharmacovigilance is a crucial process that aims to guarantee that patients are prescribed safe pharmaceuticals. The World Health Organisation describes it as "the discipline of science and activities relating to the identification, evaluation, comprehension, and avoidance of adverse effects and other drug-related problems." Recent advances in science have led to a major expansion in the role of medical devices in the healthcare delivery system. PV encompasses issues relating to medication therapy as well. To regulate the import, manufacture, sales, and distribution of medical equipment, the Indian government, along with the Drugs Technical Advisory Board, recently established the Medical Equipment Rules, in 2017. Postmarketing surveillance carried out by an Indian regulatory authority (MvPI) is becoming increasingly popular, comparable to that of international regulatory agencies. An essential instrument for protecting users from unforeseen effects and improving their health and safety, the adverse events reporting system (ADERS) allows for the recording of all types of medical device adverse events (MDAEs).

Keywords:- *Materiovigilance, Pharmacovigilance, Medical Devices, Indian Pharmacopoeia Commission, Central Drug Standard Control Organisation*

I. INTRODUCTION

Materiovigilance refers to an extensive system of performance characterization, monitoring, identification, collecting, reporting, and analysis of any unfavorable occurrence caused by medical devices. Medical technology has a major role in the diagnosis, prevention, and treatment of many diseases. Recent advances in science and technology have led to a major expansion in the use of medical devices in the healthcare delivery system.[1] The importance of medical devices in the healthcare delivery system has significantly expanded due to recent scientific innovation breakthroughs. More than a million medical gadgets are on the market, ranging in price from straightforward, inexpensive bandages or tongue depressors to expensive, sophisticated equipment like magnetic resonance imaging scanners and medical software. Any "instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or another similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific medical purpose(s) of diagnosis, prevention, monitoring, treatment or alleviation of disease, diagnosis, monitoring, treatment, alleviation of or compensation for an injury, investigation, replacement, modification, or support of the anatomy or of a physiological process, supporting or sustaining life, control of conception, and disinfection of medical devices providing information utilizing in vitro examination of specimens derived from the human body; and does not achieve specific medical goals Medical gadgets have many advantages for patients, but there are also considerable possible hazards.[1,2] The gadget has been recalled on several occasions, either because of a flaw or because it significantly increased the risk of serious illness and death among users. Therefore, at every step of the device's creation and use, it is crucial to evaluate and determine the risks and advantages related to it. A strong monitoring system, which is currently only used in a few nations, can help achieve this. [2]

II. PHARMACOVIGILANCE AND EMERGENCE OF MATERIOVIGILANCE

The science of pharmacovigilance, or Pv, is concerned with the ongoing detection, appraisal, and prevention of acute and long-term adverse effects brought on by both recently and previously marketed medications. These days, PV also includes problems associated with drug therapy-related problems (DTRPs) that are demonstrated by herbal remedies, medical gadgets, vaccines, biologicals and blood products, and traditional, complementary, and alternative medicines (TCAMs). [4] These days, pharmacoepidemiologic studies are widely used to assess the efficacy and safety of medications in clinical settings. While Materiovigilance (Mv) focuses on medical device adverse reactions and preventive measures, it shares Pv's reporting objectives and methodologies. Devices may, for instance, cause unfavorable occurrences as a result of poor design or manufacturing, poor maintenance, illogical storage, and logistics, inadequate user instructions or training that results in wrong use, off-label or unapproved use, and a host of other context-specific difficulties. Therefore, all medical gadgets have some risk, just like all medications. To improve the quality and performance standards of these devices, it is necessary to monitor their safety to remove potentially dangerous or dangerous items from the market and to remove any deficiencies. [5]

ISSN No:-2456-2165 https://doi.org/10.38124/ijisrt/IJISRT24MAY509

III. GLOBAL MATERIOVIGILANCE INITIATIVES

A group of ten nations, including the United States, Japan, the European Union, China, South Korea, and India, called the International Medical Device Regulators Forum (IMDRF) was established in 2011 to introduce and implement the Mv program to monitor adverse events (MDAEs) associated with medical devices and to harmonize international medical device regulation through Mv. Launched on July 6, 2015, the India materiovigilance Programme (MvPI) assists in gathering safety data on device use from the country's population in a methodical manner, monitoring medical device adverse events (MDAEs), educating healthcare professionals about the importance of reporting these events, balancing benefits and risks, producing evidence-based recommendations for safety, and informing relevant parties and regulatory bodies of findings. [5,6]

IV. MATERIOVIGILANCE IN INDIA

In India, the 1940 and 1945 Drug and Cosmetic Acts and Rules govern the safety, efficacy, and specifications of medical devices. For a considerable amount of time, India lacked an adequate method to track the unfavorable occurrences linked to the usage of medical devices. [4] The Medical Equipment Rules, 2017 were recently released by the Indian government in collaboration with the Drugs Technical Advisory Board to control the import, production, sales, and distribution of medical equipment. The notification was sent out on January 31, 2017, and it became effective on January 1, 2018. Materiovigilance is the term used to describe the careful observation of any unfavorable events that arise from the use of medical devices. This is done by putting in place a system that includes identifying, gathering, reporting, and estimating unfavorable events and responding to them, or taking safety corrective action once the device has reached the postmarketing phase. [7] On July 6, 2015, the Drugs Controller General India introduced the Indian Pharmacopoeia Commission (IPC) in Ghaziabad with the introduction of the Materiovigilance Programme of India (MvPI). The main objectives of this program are to track adverse events (MDAEs) related to medical devices, educate healthcare professionals about the significance of reporting MDAEs, and produce and disseminate independent, reliable, evidence-based safety data about medical devices. The Central Drug Standard Control Organisation (CDSCO) is the MvPI regulator, and the International Police Corps (IPC) is the National Coordination Centre (NCC). Ten medical colleges in four regions of India will be enrolled in this program to encourage voluntary reporting at first. Later on, the program will be expanded to include all private and public healthcare delivery systems, an e-reporting system will be developed, and reporting will be required of device manufacturers and healthcare providers.[8]

V. FRAMEWORK OF MVPI IN INDIA

An independent organization under the government's Ministry of Health and Family Welfare is the Indian Pharmacopoeia Commission of India, serving as MvPI's national coordinating center (NCC). IPC is primarily in charge of keeping an eye on and evaluating the caliber of adverse incidents involving medical devices from across the nation. The NCC is governed by several committees that suggest protocols and guidelines for regulatory interventions. The steering committee oversees all administrative matters and maintains tabs on the MvPI program, providing it with appropriate direction. The working group addresses technical matters about the program's creation and execution, as well as providing technical advice to CDSCO regarding regulatory interventions involving medical devices. For quality, technical, training, and adverse event signal-related issues, the working group may designate a core technical committee. [8] This committee will be in charge of quality assessment, technical issue resolution, medical device signal generation, and validation, as well as planning and delivering MvPI training. The healthcare technology branch of the National Health System Resource Centre (NHSRC) in Delhi provides technical assistance and serves as a resource center for the Indian materiovigilance program.[7]

➢ *The MVPI Aims are*

- Sharing safety-related information with different industry stakeholders
- Coordinating data management and information sharing with foreign authorities and other healthcare organizations.
- Analysing a medical device's benefit-risk ratio
- Establishing a national strategy for patient safety monitoring
- Aiding the Central Drugs Standard Control Organisation (CDSCO) in its decision-making regarding national medical device regulation
- Assembling data based on evidence for medical equipment connected to unfavorable outcomes

In addition to asking the Adverse Drug Reaction Monitoring Centres under PvPI for adverse event reporting, the IPC, acting as NCC for MvPI, currently oversees 150 of these MDMCs throughout India. Through a variety of reporting systems, PvPI and MvPI stakeholders receive frequent training in reporting. The NCC actively collaborates with the parties involved to improve the reporting culture for adverse occurrences (medical devices). By emphasizing patient safety broadly, lobbying and education raise awareness of the fact that reporting adverse events is our ethical and professional obligation. According to the 2017 Medical Devices Rules, the Central Licencing Authority must receive reports of all adverse events involving medical devices from the Marketing Authorization Holder. CDSCO. They also send a copy of these unfavorable occurrences to MvPI in the interim. To determine whether there are any temporal links between the reported adverse event and the medical device malfunction, the MvPI conducts an initial

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assessment of the reported adverse events and a root cause analysis of the required adverse event. Once a significant decision has been reached, the NCCMvPI reports to CDSCO. [6,8] Furthermore, all MDMCs receive medical device alerts from NCC-MvPI so that they can actively monitor any suspected medical devices. Additionally, NCCMvPI informs the public about medical device safety and encourages them to report unfavorable incidents brought on by home medical equipment. [8]

VI. INDIAN POSTMARKETING SURVEILLANCE APPROACH

Postmarketing monitoring conducted by an Indian regulatory body (MvPI) is progressively gaining traction on par with those of international regulatory bodies. Even while the overall number of reported adverse occurrences has increased annually—from 40 in 2015 to 897 in 2019—they are still smaller than those in other nations in terms of recall and other safety considerations in addition to the cumulative number. For a variety of causes, the USFDA recalled 30 medical devices in 2017 and 32 marketed medical devices in 2018. 5348 reports of adverse events were received by an Australian regulatory authority (TGA) during 2017 and 2018. Following an analysis of these incidents, 41 hazard alerts and a recall of 27 goods were issued. The TGA created 5129 signals and received 5874 adverse events in 2018–2019, which led to the recall of 55 items and the creation of 68 hazard alerts. During this time, Health Canada also recorded a higher number of recalls.[9] However, during this time, there were very few safety signals or recall actions brought forth by MvPI as a result of documented adverse incidents. It highlights how MvPI has made significant progress in terms of gathering data, evaluating adverse events, and generating signals for recall actions. Only authorized medical colleges and hospitals, independent institutes, and importers are still able to collect data. It is necessary to encourage greater participation from private hospitals, assisted living facilities, and labs. Furthermore, the MvPI-generated data is not publicly available, which hinders stakeholders' and manufacturers' ability to take immediate corrective action in the event of an unfavorable incident. [9,10]

VII. SIGNIFICANCE OF MATERIOVIGILANCE

As a modified novel branch of Pv, Mv arose to improve patient safety and health by lowering the frequency of MDAEs, creating a framework and system for national patient safety monitoring, producing evidence-based data on the safety of medical devices, evaluating the risk-benefit ratio, and informing stakeholders. To prevent future adverse occurrences, Mv also works with national and international agencies on MDAE reporting and investigation. This helps the regulatory authorities make judgments about medical devices. It assists professionals with illness or injury diagnosis, tracking, management, or mitigation. To prevent complications from counterfeit or subpar medical devices, such as device breakage and malfunction, entry- and exit-site infections, organ perforations or injuries, need for surgery, and even death, Mv also enables manufacturers to improve the design and efficiency profiles of medical devices.[11]

VIII. MEDICAL DEVICES ASSOCIATED ADVERSE EVENTS REPORTING

Global uniformity in device classification and approval processes—or, if that's not feasible, at least transparency—are significant issues that need to be addressed. Every type of MDAE, whether it be critical or non-critical, known or unknown, associated with insufficient or incomplete specifications, or unusual or frequent occurrences, needs to be recorded and assessed on an individual basis as well as overall. Device descriptions together with any known risks or hazards from prior use might also be reported. [12] All forms of medical device adverse events (MDAEs) can be recorded using the adverse events reporting system, which is a vital tool for safeguarding users against unanticipated consequences and enhancing their health and safety. The Global Harmonisation Task Force (GHTF) offers manufacturers advice on how to handle and determine whether an incident has to be reported, along with information on reporting medical device errors. [13] The FDA mandates that medical device malfunctions or serious adverse events (SAEs) be reported by importers and manufacturers in the United States.[14]

IX. ROLE OF HEALTH PROFESSIONALS IN REPORTING DEVICE-RELATED ISSUES

Building and strengthening individual and institutional capacity to report and address the harmful effects of medical devices is one way that health professionals, including surgeons, doctors, nurses, and chemists, can address concerns linked to these devices. [15] The database information system that creates signals for medical equipment can help with this. Since the primary goal is to establish and nurture an institutional culture for reporting MedSafe events to prevent future occurrences, they can also instruct and train patients and other colleagues to heighten their understanding of the significance of Mv in device recalls should a defect arise in practice. [16]

- *Regulatory Gap*

India lacks the same MvPI criteria as the US and the EU for their post-marketing surveillance programs regarding the safety of medical devices. [17] It is necessary to design the instruments and standards for signal identification and to validate the causality evaluation. On paper, MvPI seems solid, however, the annual performance report that details data collection and submission from MvPI and monitoring centers has not yet been released. The public does not have access to the analysis of reported adverse occurrences or the responses made to them. The alerted list still excludes a large number of devices. [17,18]

- *Penalties for Device Failure*

The top ten large medical device companies in the US have paid doctors and their clinics more than 600 million dollars because it is essential for pharmaceutical and medical equipment manufacturers to cover their liabilities. [19,20] A company by the name of Olympus Corporation of America was ordered by a court to pay around 623.2 million dollars in 2016 due to allegations that they had bought off physicians

ISSN No:-2456-2165 https://doi.org/10.38124/ijisrt/IJISRT24MAY509

and every member of the hospital staff. A different business, Medtronic Inc., was hired to compensate a patient for $2.8 million because the medical system was paying doctors bribes to utilize defective and malfunctioning medical equipment, which drove up the cost of treatment. [20]

X. CONCLUSION

Because they are such an essential component of the healthcare system, the use of medical devices has increased recently. Despite this, insufficient safeguards exist to shield patients against the unfavorable events linked to the use of medical equipment. The goal of the materiovigilance program is to examine, assess, and stop the recurrence of adverse effects that result from using medical devices. Despite being a complicated discipline unto itself, it needs the assistance of numerous fields, such as clinical medicine and clinical/biomedical engineering. MvPI is a commendable endeavor to guarantee the security of medical devices for Indian device users. The MvPI guidance document outlines the policy guidelines, methods, and roles and responsibilities of many stakeholders to facilitate the systematic collection of safety data. By stopping the recurrence of negative effects and lowering the risk associated with using medical devices for the greatest benefit of patients and carers, it is anticipated that the successful execution of this program would significantly protect the safety of device users.

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