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Review Article

Materiovigilance programme of India: a step towards patient safety

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ABSTRACT

Medical devices which are indispensable part of healthcare delivery system may cause serious events for patients and contribute to healthcare costs. The robust materiovigilance programme will lead to improve the safety of patients and users by reducing the reoccurrence of the incidents. Furthermore, the existing incidents advocate continuous monitoring of medical devices in use, in order to protect the patients' health. Post marketing surveillance of medical devices is done in many countries, but it is still not as developed and robust as that of medicines. Materiovigilance program of India was launched, at Indian pharmacopeia commission to monitor the adverse events associated with the use of medical devices, to generate safety data, create awareness among the different stakeholders, and recommend the best practices and interventions to improve the patient's safety. This article reviews regulations and guidance documents regarding medical devices focused on post market vigilance framework in India along with measures for robust implementation of the existing programme.

Keywords: Medical devices, Materiovigilance, Global harmonization task force

INTRODUCTION

Health technologies are essential for a functioning health system. Medical devices in particular are crucial in the prevention, diagnosis and treatment of illness and disease, as well as patient rehabilitation.[1,2] With the advancement in the technology and increased public demand for high quality medical care, more than 500,000 distinct types of medical devices are available in the market globally depending upon their distinct roles and technologies. In addition to this, over 10,000 patent applications have been filed in this field in Europe in 2012 making the medical technology industry leader in innovation.[3] An intensive amount of money is invested by the governments on medical devices, the global medical device industry has surpassed USD 350 billion in annual revenue, and in India a growth rate of 20% has been seen in healthcare industry. Nearly 5,000 individual classes of medical devices, tens of thousands of medical device suppliers, and millions of healthcare providers exist worldwide, benefits the patients immensely, they also carry significant potential risks. A variety of medical devices are being used in hospitals and clinics like ventilators, vital sign monitors, infusion, and injection pumps, as well as consumables which are the fundamental elements for proper functioning of hospitals.[4] The outcome of an adverse event related to medical devices can be serious and result in illness, injury or even death, leading to recall of medical device.[5-7] There have been many incidences of serious medical devices adverse event reported in India such as death of new-born due to incubator overheating, failure of defibrillator leading to electrical burn injury and discharge of metal ions in the blood and soft tissues following hip replacement surgery. Therefore, it is crucial to evaluate and determine the risks and benefits associated with the use of device. This can be achieved by a vigorous monitoring system for risk management of medical devices to assess qualitative effective and safe use of medical devices in the market. Keeping this objective in mind materiovigilance

programme of India was launched by the government of India.[8]

For determining the key areas that require support for the development or improvement of health technology programmes in countries and regions, the first WHO baseline country survey on medical devices was developed in 2009, which was launched in February 2010 which was updated with a re-launched in November 2013 with regular annual updates thereafter. This survey gave vital inputs regarding availability of specific medical devices, policies, guidelines, standards and services for medical device assessment, management and regulation.[9] International medical device regulators forum (IMDF) an international organization was established in 2011 with the goal of accelerating the harmonization of international medical devices regulation and to strengthen the foundation of global harmonization task forces (GHTF). It has representation of 10 countries i.e., Australia, Brazil, Canada, China, European Union, Japan, Russia, Singapore, South Korea and USA in the IMFD management committee. international medical device regulators forum (IMDRF) aims to encourage global convergence, capitalising resources and making available safe and effective medical devices globally. Global harmonization task forces (GHTF) were founded on 1992by the governments and industry representatives of Australia, Canada, Japan, the European Union, and the United States of America to respond to the growing need for the international harmonization of standards and regulatory practices related to the safety, performance and quality of medical devices. Global harmonization is the aligning of the different regulatory systems of the world to make them globally on par with each other to manufacture and sell safe and effective devices, it is responsible to harmonize global approaches to the safety, efficacy, clinical performance, and quality of medical devices with the goal of protecting public health, promoting innovation, and facilitating international trade. It has four study groups, dealing with product approval–related issues, post market surveillance, quality system requirements, and audits of quality systems.[10,11] Materiovigilance is the surveillance programme related to the medical devices was launched on 6 July 2015 at the Indian pharmacopoeia commission (IPC), dealing with the identification, collection, reporting, and prevention of adverse events associated with the use of medical devices along with its possible management to safeguard patient health The programme is meant to monitor medical device-associated adverse events (MDAE), create awareness among healthcare professionals about the importance of MDAE reporting in India and to monitor the benefit-risk profile of medical devices. In India, the medical devices rules (MDR) were notified on January 31st 2017 and became effective from January 1st, 2018. The MDR, in synchronization with MvPI, can significantly impact the post marketing surveillance of medical devices among the healthcare professionals, by ensuring their quality and thus ensuring patient/user safety. Every country has its own regulatory body and guidelines for monitoring and reporting of adverse events due to medical devices.[12,13]

Medical devices

Definition and classification among different countries of the world

Definition

The WHO has defined "medical device" as any instrument, apparatus, reagent for in vitro use, implant, device for tissue cutting or wound covering, highly sophisticated computerized medical equipment, software or other related or similar materials which are intended to be used for diagnosis, prevention, monitoring, treatment of disease.[14,15]

FRAMEWORK OF MVPI (GUIDANCE DOCUMENT MATERIOVIGILANCE PROGRAMME OF INDIA VERSION 1. 2)

Indian pharmacopoeia commission

It is an independent institution of Ministry of Health and Family Welfare, Govt. of India and functions as national coordination centre (NCC) for MvPI. IPC is mainly responsible for monitoring and assessing the quality of adverse events of medical devices from all over the country. NCC operates under the supervision of various committees which recommend procedures and guidelines for regulatory interventions

Steering committee

Steering committee is mainly responsible for all administrative issues and to keep track of MvPI programme thus giving proper direction to the MvPI programme

Working group

It deals with technical issues related to establishment and implementation of programme and giving technical inputs to CDSCO for regulatory intervention of medical devices. Working group may appoint core technical committee for quality, technical, training and adverse event signal-related issue

Technical core committee

It is mainly responsible for quality assessment, resolving the technical issues, signal generation and validation related to medical devices and organizing and providing training on MvPI.

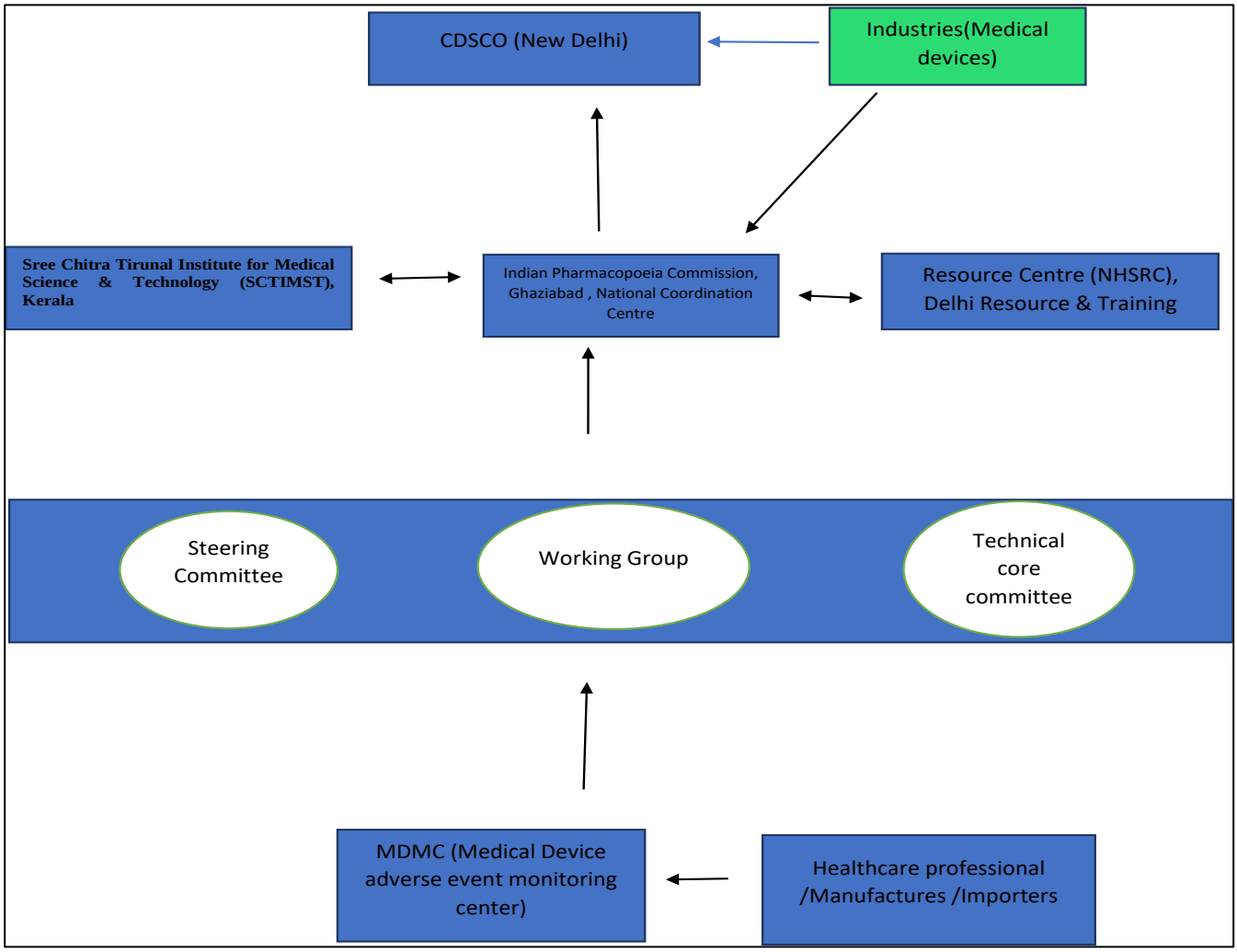

Figure 1: Flow of information of adverse event related to medical devices.

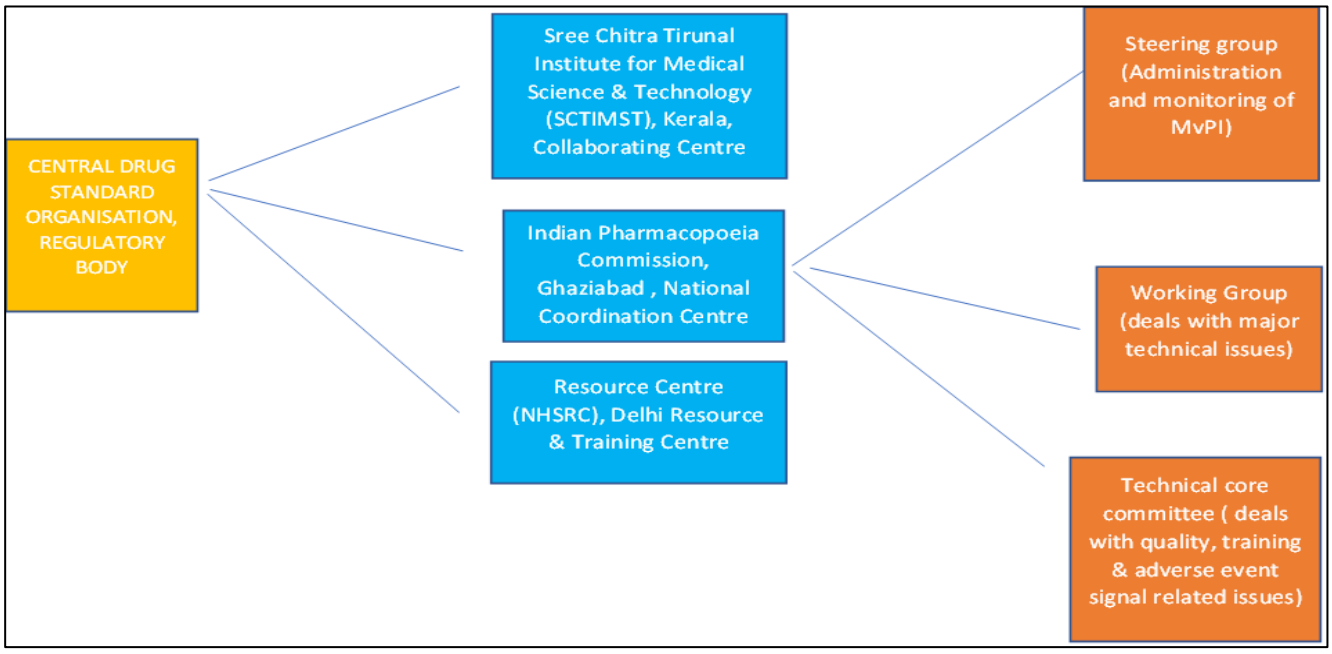

Figure 1: Organizational Framework of Materiovigilance programme of India. (MvPI).

Sree Chitra Tirunal institute for medical science and technology (SCTIMST), Kerala

Sree Chitra Tirunal institute for medical sciences and technology (SCTIMST) an institute of national importance with the status of a university in 1980 under department of science and technology, GOI functions as collaborating centre for MvPI. Its main duty is to develop the state of art facilities that would not be available elsewhere in country such as new biomedical devices and products, evaluation of medical devices to global specifications, new academic programmes and global public health networks.

National health system resource centre (NHSRC), Delhi

healthcare technology division of NHSRC gives technical support and act as resource centre for the materiovigilance program of India. Framework of MvPI has been presented in Figure 1 and information flow in case of adverse event related to medical devices was presented in Figure 2.

OBJECTIVES OF MATERIOVIGILANCE PROGRAM OF INDIA

The program was initiated with the objectives to protect the health and ensure the safety of device users and others by reducing the recurrences of adverse events and malfunctions.

To build a nationwide system for medical device related adverse effects for patient safety monitoring. to generate awareness among healthcare professionals about the significance of MDAE reporting, to examine the risk–benefit ratio and perform causality assessment of medical devices, to establish evidence-based data on the safety of medical device, to support CDSCO in making decisions about medical devices regulation in the country based on data generated in India, to generate autonomously, evidence-based recommendations on the safety of medical devices and to issue medical device alert to regulators and health professionals, to impart the safety information on the use of medical devices to various stakeholders to minimize the risk for patient safety, to emerge as a national centre of excellence for materiovigilance activities and to amalgamate with other healthcare organizations and international agencies for the information exchange and data management.[14-16]

Documenting and reporting adverse events

To encourage the habit of reporting, all types of adverse events related to medical devices used in India irrespective of whether they are known or unknown, serious or nonserious, frequent or rare can be reported. Along with that any malfunction or deterioration in characteristics or performance of medical device, incorrect or out of specification test result, discovery of design flaw and inaccuracy in labelling or instructions for use can be reported. A reporting format, two pages medical device adverse event reporting form has been prepared by MvPI which contain all information in detail regarding the patient, adverse event, device, regulator, and reporter. This form is freely available on the official website of IPC (www.ipc. gov.in). Reporters from MDMCs after filling the above mentioned MDAE reporting form can submit it to the coordinator or Research Associate of the respective MDMC. A reporter who is not part of MDMC can submit the filled MDAE reporting form to the nearest MDMC or directly to the National Collaborating Centre. Reporter can also mail the scanned form at lab.ipc@gov.in and copy to mvpi.ipcindia@gmail.com. The reporter can also call the helpline number created by NCC-PvPI (1800-180-3024) and report the adverse event. Documenting and reporting adverse events due to the device and immaculate flow of information involves various aspects and interrelationship among different stakeholders-Role of health-care service providers, role of manufactures, role of research associate and coordinator at MDMC, the responsibility of national collaborating centre, the responsibility of national coordinating centre (NCC), the responsibility of technical support and research center (TSRC) and the responsibility of CDSCO.[16,17]

Role and responsibilities of different units of materiovigilance program of India

MDMC collect and review the completeness of MDAE, analyse failure mode effect, assess causality as per the standard operating procedures (SOP), and send the monthly consolidated report to National collaborating centre. As per the guidance documents of MvPI 10 medical colleges in different parts of the country had been identified as MDMC. Currently 174 Medical devices monitoring centres (MADC) have been enrolled in materiovigilance programme of India out of which 13 are there in Maharashtra. These MDMCs should report cases to NCC -IPC every month for review and analysis. The national collaborating centre assemble the adverse event report from MDMC, collates, analyse them, perform signal detection and communicate the outcome to NCC. It is also involved in conducting awareness program, training, and the workshop on materiovigilance periodically at various zones of the country. The main responsibility of Indian Pharmacopoeia Commission which functions as MvPI-NCC is to harmonise with all stakeholders of the program by convening steering committee and working group meetings. The other responsibility of it is to recognize new MDMCs across the country. It also prepares and disseminates SOP, guidance documents, training manual, and newsletter. It formulates the data received from SCTIMST and recommend to the CDSCO for appropriate action. DGCI-CDSCO formulates the regulatory decisions and communicates to the different stakeholders. As regulator, it is also incumbent upon CDSCO to join IMDRF and other international forums for exchange of post marketing safety information. National health system resource centre ministry of health and family welfare, government of India, New Delhi, functions as TSRC. It provides technical support to NCC for the preparation of

SOP, guidance documents, newsletters, and training manuals. It also helps in identifying new MDMC.[18,19]

CONCLUSION

Medical devices are indispensable part of healthcare system leading to rise in the use of medical devices in recent years. Despite that, there are not adequate measures to protect the patients from the untoward incidences associated with the use of medical devices. Materiovigilance program is meant to analyse, scrutinize, and prevent the recurrence of harmful effects occurs due to use of medical devices. Although it is a complex science in itself which requires the support of many domains including clinical medicine as well as clinical engineering/biomedical engineering. MvPI is a good initiative to ensure the safety of medical devices among the device users in India. The guidance document of MvPI has laid down the policy guidelines, procedures, and clarified the role and responsibilities of different stakeholders to enable safety data collection in a systematic manner. It is expected that effective implementation of this program will safeguard the safety of device users substantially by preventing the recurrence of adverse effects and reducing the risk associated with the use of medical devices for the maximum benefit to the patients as well as care providers.

For the robust implementation of the materiovigilance programme association of the health care professionals (HCP) is of paramount importance. Sensitization of HCP can be done by conducting CME to increase awareness of HCP about MvPi, updation of the syllabus of health care and paramedical courses to incorporate MvPI, forming medical devices registry at hospital level and incorporation of MvPi to NABH fulfilment criteria.

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