

REVIEW ARTICLE

Materiovigilance: Current status in India analogous to its global status

Nalini Pandey ^{a,*}, Mohammed Imran ^b

^a Pharmacovigilance Associate, Department of Pharmacology, Maharishi Markandeshwar Medical College & Hospital, Sultanpur, Kumarhatti, Solan, India

^b Professor & Head of the Department, Department of Pharmacology, Maharishi Markandeshwar Medical College & Hospital, Sultanpur, Kumarhatti, Solan, India

ARTICLE INFO ABSTRACT



Received 14 September 2020;
Revised 30 October 2020;
Accepted 16 November 2020.

Keywords:

Medical devices,
materiovigilance
programme of India,
global harmonization of
task force, Indian
pharmacopoeia
commission

Introduction: Medical devices are boon to the healthcare system and are available in the market since long ago. More than 500,000 different types of the medical devices are available in the international market. Thus, from the patient safety view point, assessment of the quality and safety of these medical devices is essential.

Objectives: This review article discusses the classification and regulation of medical devices in India and the world with framework of adverse event reporting system for medical devices in India.

Methods: To address the aforesaid issue International Medical Device Regulators Forum (IMDRF) was established in 2011 was established at international Level. In India, 4 years later in 2015, Materiovigilance Program of India (MvPI) was introduced with the prime aim of improving the protection of the health and safety of patients, healthcare professionals and others by reducing the likelihood of reoccurrence of an adverse event associated with the use of medical devices.

Results: At present, there are 50 Medical Device Adverse Event Monitoring Centres (MDMCs) in India. Every country has its own regulatory body and guidelines for monitoring and reporting of adverse events due to medical devices eg: USFDA in USA, TGA in Australia, MHRA in UK, ENVISA in Brazil, CDSCO in India etc.

Conclusions: In India, the provisions of regulation of safety, quality and performance of medical devices are laid down in the Drugs and Cosmetics Act, 1940 and rules 1945.

An official publication of Global Pharmacovigilance Society.

Introduction

Medical devices, boon to the healthcare system, has been there in the market since long ago. It is an integral part of healthcare practices for saving the life of the patients. 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 (Mirel *et al.*, 2014). An intensive amount of money is invested by the governments on medical devices. For instance, in 2000, US\$ 145 billion were spend on 1.5 million different medical devices ("Medical Devices Regulation", 2003). Yet there are many countries which



* Corresponding Author

Nalini Pandey

E-mail: pandey.nalini110@gmail.com

Contact: +918629066334

* Copyright: 2582-7235 // © 2020 The Author(s).

Published by Global Pharmacovigilance Society.

This is an open-access article under the [CC BY-NC-ND license](https://creativecommons.org/licenses/by-nc-nd/4.0/).



Available online 1 December 2020

lack the assess to high quality of medical devices putting the health and life of patient to high degree risk.

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 (Alsohime *et al.*, 2019). With reference to USA in 2006, number of injuries related to devices use were about 116086 and 2830 deaths due to devices were documented. And in response to foresaid fact 4146 devices were recalled from the market between the period 2000 to 2006 (Mirel *et al.*, 2014; McGee *et al.*, 2012). From 2000 to 2011 in Australia, 6812 medical devices associated incidents were documented but analogous to large number of documented incidents only 35 medical devices were recalled and only 34 alerts regarding medical devices were realized (McGee *et al.*, 2012). Thus, there is a need of monitoring system for risk management of the medical devices available in the market so as to enable the assess to qualitative, effective and safe medical devices in the market.

To address the problem of regulation regarding medical devices, World Health Organization conducted the first WHO Baseline Country Survey on Medical Devices in 2009, which was launched in February 2010 and was updated with a re-launch in November 2013. Since then, annual updates are being undertaken. This survey gave the information regarding availability of specific medical devices, policies, guidelines, standards and services for medical device assessment, management and regulation ("Global atlas of medical devices", 2017). An international organization with the appellation International Medical Device Regulators Forum (IMDRF) was established in 2011 with the primary aim of accelerating the harmonization of international medical devices regulation and to strengthen the foundation of Global Harmonization Task Forces (GHTF). IMDRF management committee is constituted by 10 countries i.e. Australia, Brazil, Canada, China, European Union, Japan, Russia, Singapore, South Korea and USA. IMDRF seeks to foster global convergence, leveraging resources and making available safe and effective medical devices globally ("International Medical Device Regulators Forum"). GHTF was founded on 1993 by the governments and industry representatives of Australia, Canada, Japan, the European Union, and the United States of America with the aim of encouraging convergence in standards and regulatory practices related to the safety, performance and quality of medical devices ("Global harmonization Task Forces"). It believes in dissemination of information regarding the medical devices across the globe so as to generate the awareness regarding the safe use of medical devices and reporting of adverse event related to medical devices in general public.

In India the surveillance programme related to the medical devices was launched on 6 July 2015 at the Indian

Pharmacopoeia Commission (IPC), Ghaziabad by Drug Controller General of India with the name Materiovigilance Programme of India (MvPI). Materiovigilance is the monitoring programme 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 (Chauhan *et al.*, 2019). Every country has its own regulatory body and guidelines for monitoring and reporting of adverse events due to medical devices.

Medical devices: Definition and classification among different countries of the world

A. Definition:

The World Health Organization (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 (Rani *et al.*, 2018; Chauhan *et al.*, 2019).

Department of Health, Republic of Philippines (Tamsin *et al.*, 2014) defines medical device as any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software, material or other 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 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
- disinfection of medical devices
- providing information for medical or diagnostic purposes by means of *in-vitro* examination of specimens derived from the human body;
- and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.

In India, at present only notified medical devices are regulated as Drugs under the Drugs and Cosmetics Act 1940 and Rules made there under in 1945.

- Substances used for in vitro diagnosis and surgical dressings, surgical bandages, surgical staples, surgical sutures, ligatures, blood and blood component collection bag with or without anticoagulant covered under sub-clause (i);
- Substances including mechanical contraceptives (condoms, intrauterine devices, tubal rings), disinfectants and insecticides notified under sub-clause (ii); and

- Devices notified from time to time under sub-clause (iv), of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940.

Classification of medical devices in different countries: Regulatory bodies of different countries have distinct classification of the medical devices. The same has been shown in tabular form in **Table 1.** ([Chauhan et.al., 2019](#); ["Rules for classification of Medical Devices", 2019](#); [Brazil Medical Device Regulations](#); [Medical Device Rules India, 2017](#); [Classification of Medical Devices Regulations and Regulatory Approval for Registration](#))

Table 1: Classification of Medical Devices in different countries

Countr y	Regulator y Body	Class I			Class II		Class III	Class IV
China	CFDA	Low risk eg: Medical dressing, invasive devices, reusable surgical devices			Medium risk eg: liquid transportation devices,		High risk eg: blood and other body fluids alternation devices	
New Zealand	MedSafe	Class I sterile	Class I measuring	Class I basic	Class IIa	Class IIb	High risk eg: Drug eluting cardiac stents	
		Low risk eg: Sterile dressings, non-medicated	Low risk eg: Volumetric urine bag	Low risk eg: Reusable surgical instruments	Medium to Low risk eg: Hypodermic needles, suction equipment	Medium to High risk eg: Ventilators, orthopedic implants		
India	CDSCO	Class A (Low risk) eg: Nasopharyngeal, surgical dressings, umbilical occlusion device, bolster suture, alcohol swabs etc.			Class B (low moderate risk) eg: Fiberoptic oximeter catheter, A-V shunt or fistula adapter, transcervical endoscope and accessories etc.		Class C (moderate high risk) eg: vein ablation device, uterine balloon therapy device, RF conductive MR steerable electrode	Class D (High risk) eg: radiofrequency ablation device, percutaneous conduction tissue ablation, coronary stent etc.

						catheter etc.
USA	USFDA	General controls Eg: Elastic bandage and examination gloves	General controls and special controls Eg: Infusion pumps, surgical drapes, and ultrasound imaging systems		General controls and premarket approval Eg: Heart valves, and silicone gel-filled breast implants	
Brazil	ENVISA	Low risk eg: Simple surgical instruments, tongue depressor	Low-Moderate eg: Digestive catheters, infusion pumps, and A powered wheelchairs		High-Moderate risk eg: Dialyzers, and orthopaedic implants	High risk eg: Coronary stents
United Kingdom	MHRA	Low risk eg: Dressings	Class IIa Low-medium risk eg: X-ray film	Class IIb Medium-high risk eg: Blood bags, contact lens care products	High risk eg: Bone cement, cardiac stents	
Australia	TGA	Low risk Eg: Surgical microscopes and examination lights	Class IIa Low to medium risk eg: Electrical acupuncture and warming blankets	Class IIb Medium to high risk eg: Infant incubators and external defibrillators	High risk Eg: Heparin-coated catheters and biological heart valves	Active implantable medical device (AIMD) eg: Contraceptive intrauterine devices

Regulation of Medical devices in India

Under the medical devices rules, 2017, import, manufacture, clinical investigation, sale and distribution are being regulated. This rule also specifies the classification of

medical devices which is dynamic and subjected to amendments from time to time. The provisions made under the Drugs and Cosmetics Act, 1940 and rules 1945 regulates the safety, quality and performance of medical devices ([About Medical Devices](#)). To address the problem

arising due to the adverse events associated with the medical devices use, MvPI was launched on 6 July and for regulating its function nationwide, India Pharmacopoeia Commission was established as National Coordination Centre for medical devices adverse event monitoring. Sree Chitra Tirunal Institute of Medical Sciences & Technology (SCTIMST) functions as National Collaborating Centre and National Health Systems Resource Centre (NHSRC) under MoHFW, Govt. of India is working as technical support and resource centre ("Guidance Document Materiovigilance Programme of India Version1.2"). This programme came into existence with the main purpose of

monitoring the adverse event associated with medical device use along with creating the awareness of the same among the healthcare professional and to thus, appraise the benefit -risk profile of the medical device available in the market. Secondary purpose was to disseminate the information regarding the safety of medical devices among all key stakeholders which was evidence based ([International Medical Device Regulators Forum](#)). At present, there are 50 Medical Device Adverse Event Monitoring Centres (MDMCs) in India that are being shown through pie chart given below **Figure 1**.

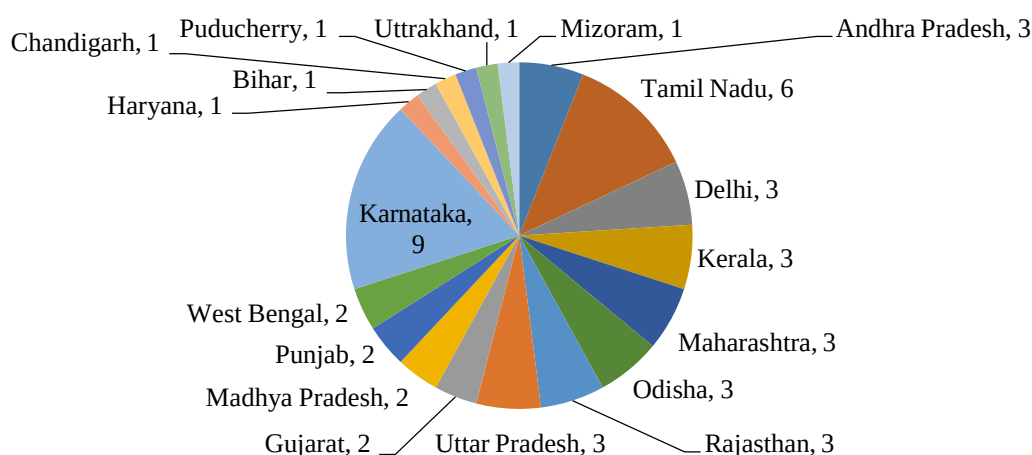


Figure 1: Medical Device Adverse Event Monitoring Centres in India

Framework of MvPI ("Guidance Document Materiovigilance Programme of India Version1. 2")

Indian Pharmacopoeia Commission

It is an autonomous body working under the aegis of Ministry of Health and Family Welfare, Govt. of India and functions as coordination centre for MvPI. IPC has the main responsibility of monitoring and assessing the quality of reports send to it regarding medical devices from all over the country. Various committees have been established under the NCC and assigned the different roles and responsibilities.

Steering Committee

It deals with all the administrative issues and responsible for monitoring the MvPI programme to lead it in a proper direction in the country.

Working group

It handles the major technical issues regarding the implementation of the programme in the country.

Technical core Committee

It deals with quality assessment, sorting out the technical issues, signal generation and validation related to medical devices and organizing and providing training on MvPI.

Sree Chitra Tirunal Institute for Medical Science & Technology (SCTIMST), Kerala

It works as collaborating centre for MvPI and its main focus is in developing the state of art facilities that would not be available elsewhere in the country such as evaluation of the medical devices to global specifications, new academic programmes and global public health networks.

National Health System Resource Centre (NHSRC), Delhi

It's main role is to provide the technical support to National Collaborating Centre and NCC including training.

The framework of MvPI has been presented in Figure 2 and the Information flow in case of the Adverse event related to medical devices was presented in Figure 3.

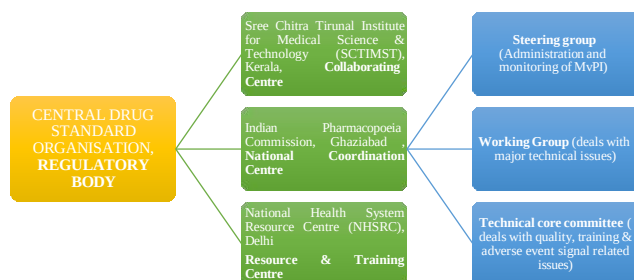


Figure 2: Framework of MvPI

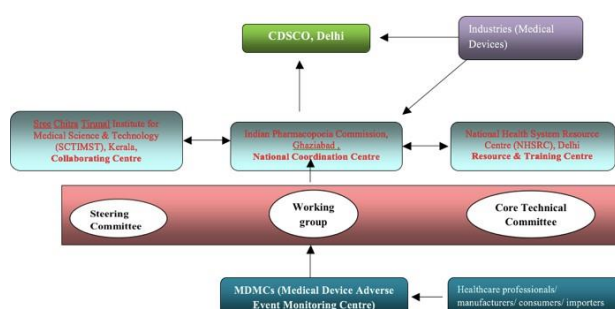


Figure 3: Information flow in case of the Adverse event related to medical devices

What needs to be reported

The adverse event with advert to medical devices include following but are not only limited to the same:

- Non-compliance or inadequate compliance of the medical device in context of safety testing eg:- validation of quality and functioning of medical devices with the standard before putting them in the market.
- Adverse event occurring due to non-declaration of the sufficient warning/ labeling for testing eg; if the manual shows the standard temperature for equipment storage is 120°C and if there has been fluctuation in the storage temperature than the standard it may lead to adverse event.
- If the frequency of adverse event occurrence is higher than the frequency reflected in the labeling after testing based on objective standards.

- Clinical Application error.
- Unintended use of medical device/ equipment/ instrument.
- Malfunction or deterioration of the characteristic or functioning of the medical device eg; failure of intrauterine devices.
- Interaction with other substances.
- Inappropriate delivery of the therapy eg: if the drug gets released immediately instead of extended one according to the manual standards.

Exceptions to reporting

There are certain events or incidences that need not to be reported.

- In case adverse event occurred due to device exceeding its expiry date along with failure mode not unusual.
- If prior to use of medical device, any discrepancies or deficiencies in device were assessed and as such no harm took place.
- In case of no injured occurred to anybody due to the fact that in-built protective mechanism in the device worked properly and prevented the harm by alarming the user about fault.
- In case of an expected and foreseeable side effect associated with medical device eg. clinically acceptable event, information that is well documented in the device master card, manufacturing labeling or clinically well known.

Who can Report

All the clinicians, users, nurses, lawyer, consumer or manufacturer or in general term everyone can report the adverse event due to medical devices.

Reporting time frame of different countries ("Final Status Document Global Harmonization Task Force", 2005; "Guidance Document Materiovigilance Programme of India Version 1.2")

The reporting authorities and the time frame for reporting in different countries

Countries	Regulatory Authority	Guidelines followed	Time frame for reporting
USA	US-FDA	21CFR803A	Device manufacturers are required to report within 30 days whenever the manufacturer receives or otherwise becomes aware of information, from any source, that

			reasonably suggests that a device marketed by the manufacturer;
			May have caused or contributed to a death or serious injury; or
			Has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.
AUSTRALIA	Therapeutic Goods Administration (TGA)	Australian Medical Devices Guidelines - Guidance Document Number 11, Version 1.7	Manufacturers or their authorized representatives are required to report adverse events occurring in Australia to the TGA as follows: - within 2 days of becoming aware of an event of significant public health threat or concern; - within 10 days of becoming aware of an event that lead to serious injury or death; and - within 30 days of becoming aware of a "near event";
CANADA	Health Canada	Canadian Medical Devices Regulations, Section 60 and 61	A preliminary report shall be submitted to the Minister in respect of an incident that occurs in Canada within 10 days after the manufacturer or importer of a medical device becomes aware of an incident, if the incident has led to the death or a serious deterioration in the state of health of a patient, user or other person, or within 30 days after the manufacturer or importer of a medical device becomes aware of an incident, if the incident has not led to the death or a serious deterioration in the state of health of a patient, user or other person, but could do so were it to recur; and in respect of an incident that occurs outside Canada, as soon as possible after the manufacturer has indicated, to the regulatory agency referred to in paragraph (2), the manufacturer's intention to take corrective action, or after the regulatory agency has required the manufacturer to take corrective action.
JAPAN	Ministry of Health, Labor and Welfare (MHLW)	[Pharmaceutical affairs law (translated by Jiho Inc. 2001) Article 77-4-2 Enforcement Regulations (translated by Jiho Inc. 2001, Inc. 2001)Article 64-5-2]	Under the current laws and requirements in Japan, manufacturers and importers of medical devices shall submit a Fuguai(AE) report to the Japanese Government. The law states that the MHLW is able to be a contact window for submission of Fuguai Reports and delegate the report reviewing function to the PMDA (Pharmaceutical and Medical DeviceAgency; one of the independent administration legal entity).
INDIA	CDSCO	Guidance Document MvPI Version 1.2	Any suspected unexpected serious adverse event incident like deaths, serious injuries, malfunction etc. and action taken thereon including any recall report Within 15 calendar days of becoming aware of an event to IPC, Ghaziabad. For non-serious events reporting to be done within 30 calendar days of becoming aware of an event to IPC, Ghaziabad

Conclusions

Although there are number of regulations over the medical devices globally but the reporting of adverse event associated with the medical devices is still inadequate. There are number of reasons for this shortfall like lack of awareness among healthcare professionals, fear of censure or legal implications, not sure in context to what needs to be reported and what not, lack of time, and prevalence of underreporting culture. This underreporting, in other terms, is dangerous as it leads to the failure of prevention of reoccurrence of any fatal event which could otherwise be prevented. Materiovigilance is a new field and government requires arduous efforts to make the HCPs, technicians, users and general public aware of this new evolving field as much as possible. The only way out to make a difference is continuous education and training of HCPs and users regarding the country as well as international guidelines and standards. It is essential for the risk management of medical devices available in the market and imported ones. Reporting culture leads to the buildup of an essential data of the country helpful for improving patient health and safety.

Conflict of Interest

There is no conflict of Interest.

References

- About Medical Devices. Retrieved from <https://cdsco.gov.in/opencms/opencms/en/Medical-Device-Diagnostics/Medical-Device-Diagnostics/>
- Alsohime, F., Tamsah, M. H., Hasan, G., Al-Eyadhy, A., Gulman, S., Issa, H., & Alsohime, O. (2019). Reporting adverse events related to medical devices: A single center experience from a tertiary academic hospital. *PLoS one*, 14(10), e0224233.
- Brazil Medical Device Regulations. Retrieved from <https://www.regdesk.co/resource-library/brazil/>
- Chauhan, P., Zarreen, A., Iqbal, M. K. (2019). Current Status Of Materiovigilance Globally-An Utter Overview With Clinical Case Perusal. *International journal of pharmacy and pharmaceutical sciences*, 11(10), 1-8.
- Final Status Document Global Harmonization Task Force. (2005). Retrieved from <http://www.imdrf.org/docs/ghtf/final/sg2/technical-docs/ghtf-sg2-n68r3-2005-guidance-adverse-event.pdf>
- George, B. (2019). Overview of current Regulations governing Medical Devices. *International journal of drug regulatory affairs*, 7(2), 62-66.
- Global atlas of medical devices (WHO Medical device technical series). (2017). Retrieved from https://www.who.int/medical_devices/publications/global_atlas_meddev2017/en/
- Global harmonization Task Forces. Retrieved from https://www.who.int/medical_devices/collaborations/force/en/
- Guidance Document Materiovigilance Programme of India Version1.2. Retrieved from <https://www.ipc.gov.in/mandates/pvpi/materiovigilance-programme-of-india-mvpi.html>
- International Medical Device Regulators Forum. Retrieved from <http://www.imdrf.org/about/about.asp#mcm>
- List of Medical Device Monitoring Centres under Materiovigilance Programme of India. Retrieved from <https://www.ipc.gov.in/mandates/pvpi/materiovigilance-programme-of-india-mvpi.html>
- McGee, R. G., Webster, A. C., Rogerson, T. E., & Craig, J. C. (2012). Medical device regulation in Australia: safe and effective?. *The Medical journal of Australia*, 196(4), 256–260.
- Medical Device Regulations: Global overview and guiding principles. (2003). Retrieved from https://www.who.int/medical_devices/publications/en/MD_Regulations.pdf?ua=1
- Medical Device Rules India, 2017: Classification of Medical Devices Regulations and Regulatory Approval for Registration. (n.d.). Retrieved from <https://morulaa.com/cdsco/medical-devices-rules-2017-classification-of-medical-devices/>
- Mirel S. et al. Materiovigilance and Medical Devices. In: Vlad S., Ciupa R. (eds) International Conference on Advancements of Medicine and Health Care through Technology; 5th- 7th June 2014, Cluj-Napoca, Romania. IFMBE Proceedings, 2014; vol 44. Springer, Cham.
- Rani, S., Singh, K. (2018). Materiovigilance: an emerging discipline. *International journal of scientific research*, 7(6), 15-16.
- Tamsin, M., Bach, C. (2014). The design of medical devices. *International journal of Innovation and scientific research*, 1(2), 127-134.