Available online on 15 Sep, 2021 at https://ijdra.com/index.php/journal

International Journal of Drug Regulatory Affairs

Published by Diva Enterprises Pvt. Ltd., New Delhi
Associated with Delhi Pharmaceutical Sciences & Research University
Copyright© 2013-21 IJDRA

Review Article

Open Access

Medical device vigilance system

Riya Patel* and Bhumika Maheriya

Graduate School of Pharmacy, Gujarat Technological University Campus, Sector-26, Gandhinagar – 382028, Gujarat, India

Abstract

The medical device vigilance is the synchronized system of to identify, to compile, to notify and to analyse of any adverse event which are connected with the use of medical devices and to defend the health of patient and also preventing relapses. In many nations, post-marketing surveillance of medical devices has begun but is not yet as established or robust as that for medicines. In USA a program has started under the name of Medical Device Reporting (MDR) and in 2015 India also introduced the Materiovigilance program by DCGI at the Indian Pharmacopoeia Commission (IPC) in Ghaziabad. Main benefit of an efficient system such as medical device vigilance in reporting the risks and safety crises of medical devices has become gradually evident in recent years. Safety issues of medical devices tend to quickly gain global significance. The speed of information spreads in the modern world means that concerns about the safety of medical devices are no longer limited to individual countries. Around the world, to improve the standard of medical devices, several measures are being taken to provide greater patient safety. The main goal of the concept turns out to be to accurately ensure the safety of the patient, as well as provided that the necessary guidance for both producers and expert authorities that allows them to monitor cases reliably and appropriately.

Keywords: Materiovigilance, Medical Device Reporting (MDR), CDSCO, adverse event, surveillance, medical device

Article Info: Received 11 Jun. 2021; Review Completed 03 Aug. 2021; Accepted 15 Aug. 2021

Cite this article as:
Patel R, Maheriya B. Medical device vigilance system. Int J Drug Reg Affairs [Internet]. 2021 Sep 15 [cited 2021 Sep 15]; 9(3):1-8. Available from:
http://ijdra.com/index.php/journal/article/view/475

DOI: 10.22270/ijdra.v9i3.475
*Corresponding author

1. Introduction

The term "vigilance" it means close monitoring of the possible adverse effects. Medical device vigilance is a study of adverse events which is associated with the use of medical devices. It deals with the closely monitoring of medical devices after post-marketing phase. The term "medical device" has been defined by the World Health Organization (WHO) 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. The medical devices provide immense benefits to the patients, but the use of medical devices may also carry some significant potential risks, sometimes life-threatening condition. (1)

Medical device vigilance refers to the close monitoring of any undesirable incident resulting from the use of medical devices by implementing a system that includes the identification, collection, reporting, and estimation of undesirable events and their reaction, or safety corrective actions after their post marketing phase. (2)

Scope and objective of medical device vigilance system

- Improve the protection of the health and safety of patients, users and others by reduce the frequency of an accident.
- Provide solutions for advancing equipment utilization and productivity.
- Create a nationwide system to monitor patient safety.
- Analyse the risk-benefit ratio of medical devices.
- Generate evidence-based information on the safety of medical devices.
- Communicate safety information on the use of medical devices to various stakeholders to minimize risk.
- To manufacturers, importers, distributors of medical devices, including all those interested in health for the promotion of patient safety and the strengthening of the materiovigilance system.

- Inform stakeholders of the need and importance of reporting adverse events for medical devices (MDAE)

Applications of medical device vigilance system

- Analysis, monitoring, prevention, treatment of disease.
- Efficacy of medical devices and also improvement of the design
- Notification and investigation of adverse events related with a medical device.
- Implementation of corrective actions to prevent adverse events in the future.
- Support and sustain life.
- Disinfection of medical devices.
- corrective safety actions after the post-marketing phase. (3)

2. Materiovigilance program in India (4,5)

Materiovigilance refers to the close monitoring of any undesirable incident resulting from the use of medical devices by implementing a system that includes the identification, collection, reporting, and estimation of undesirable events and their reaction, or corrective safety actions after the post marketing phase.

Medical device timeline

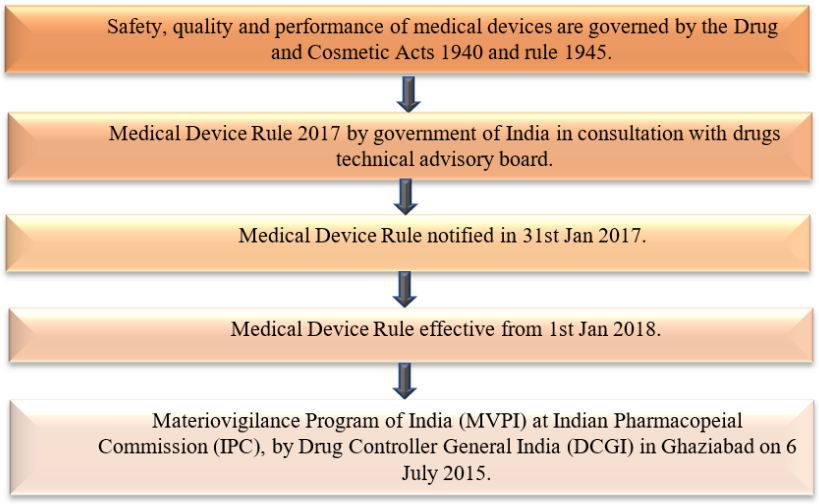

Figure 1. Medical device timeline (4)

Purpose of materiovigilance (5)

- For Medical Device-associated Adverse Events (MDAEs) monitoring,
- To increase awareness amongst healthcare professionals of the importance of MDAE reports,
- based on medical device safety data generate a reliable and independent evidence and share that evidence with stakeholders.

Regulators of materiovigilance program India

- National Coordination Centre (NCC)
- Central Drug Standard Control Organization (CDSCO)

Organizational structure of materiovigilance program in India (6)

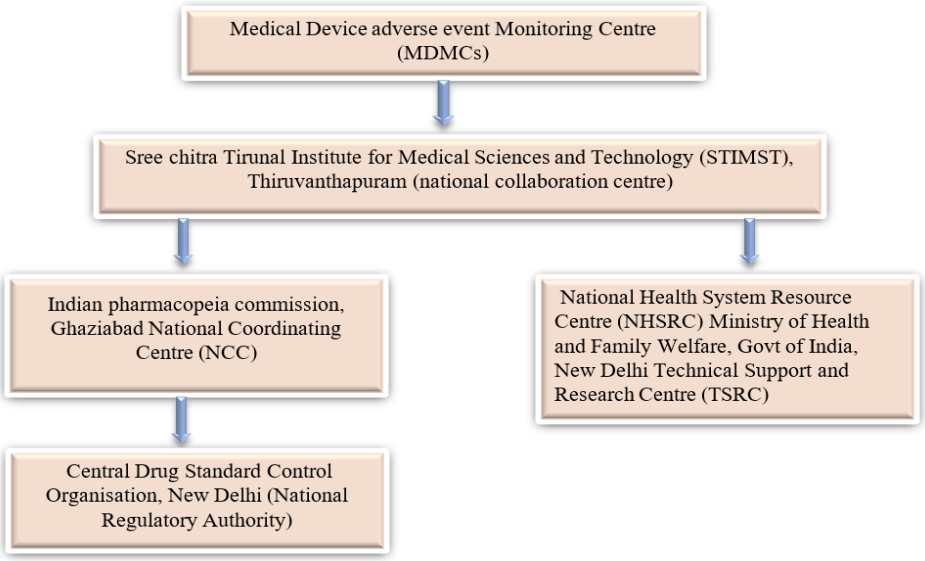

Figure 2. Organizational structure of materiovigilance program of India (6)

3. Adverse event reporting (7-10)

The adverse event reporting system helps to report adverse events. All events are associated medical device. It is considered an important archiving tool through which it is possible to report all the types of adverse events related to the medical device. (7) In India, adverse events should be reported below as:

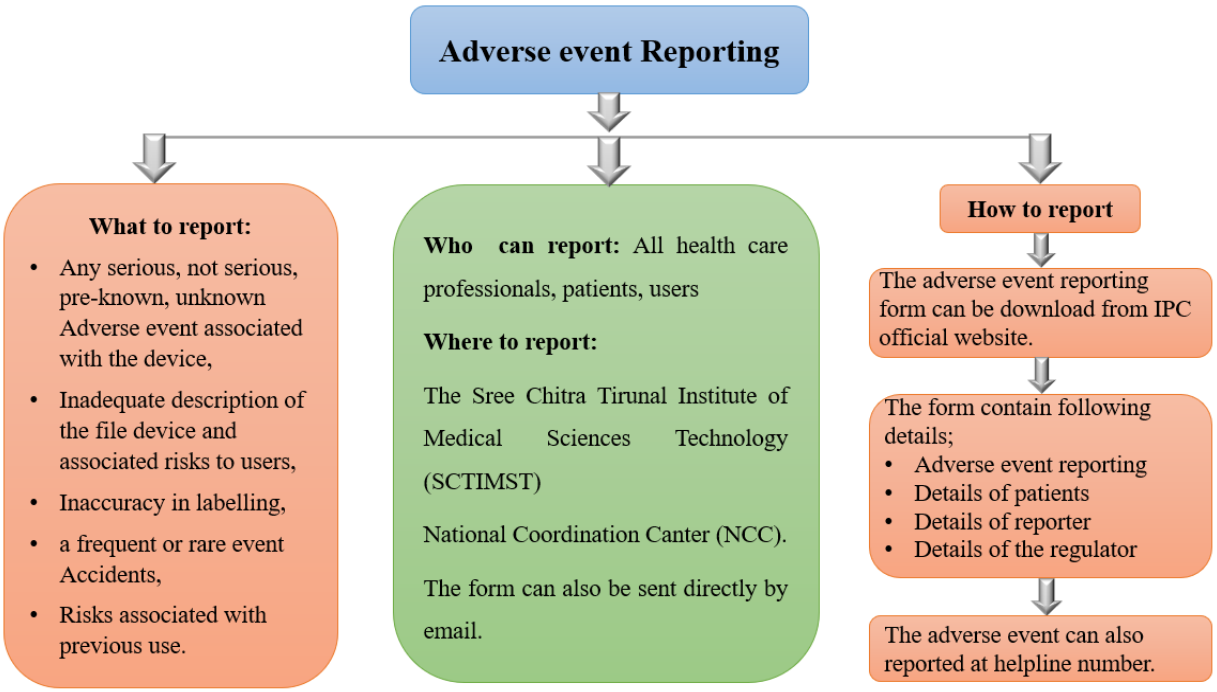

Figure 3. Adverse Event reporting (8,9)

In U.S, manufacturer and importer must be reported serious injuries, deaths and user facilities to report serious injuries and deaths to USFDA as per Medical Device Reporting Regulations (MDRs). The Medical Device Reporting Regulations (MDRs) does not necessitate overseas manufacturers to fulfil a FDA regulations, but if any employed and agent can file reports and it will be seen as an employee of an overseas manufacturing company. (9)

As per the EEC directives of UK includes to report a certain type of incidents to a competent authority such as the MHRA requirements not only for the medical device manufacturers or authorized representatives, but also for the MHRA distribute the information to other authorities, competent authorities, and EEC. (10)

4. Types of reports

GHTF has not recommended any kind of manufacturer reports. Type of report submitted by various between regulated countries, as reporting time varies. The FDA has ruled that the manufacturer must a file five types of MDR reports (11), i.e.

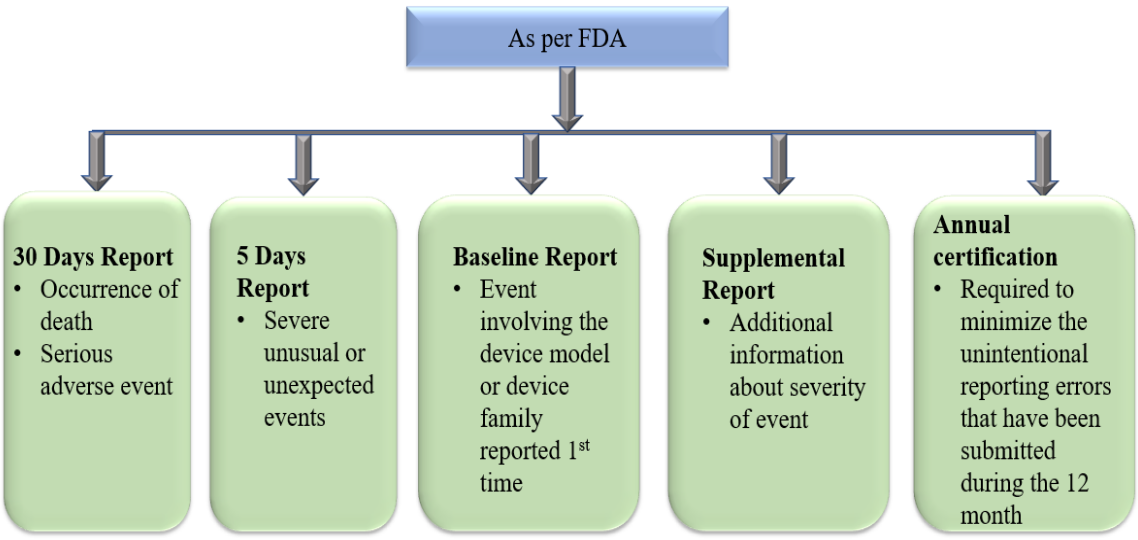

Figure 4. FDA Reports (11)

CDSCO in India has determined notification following reports (12)

Figure 5. CDSCO Reports (12)

In the UK, the manufacturer can report the incidents by submitting the following report (13)

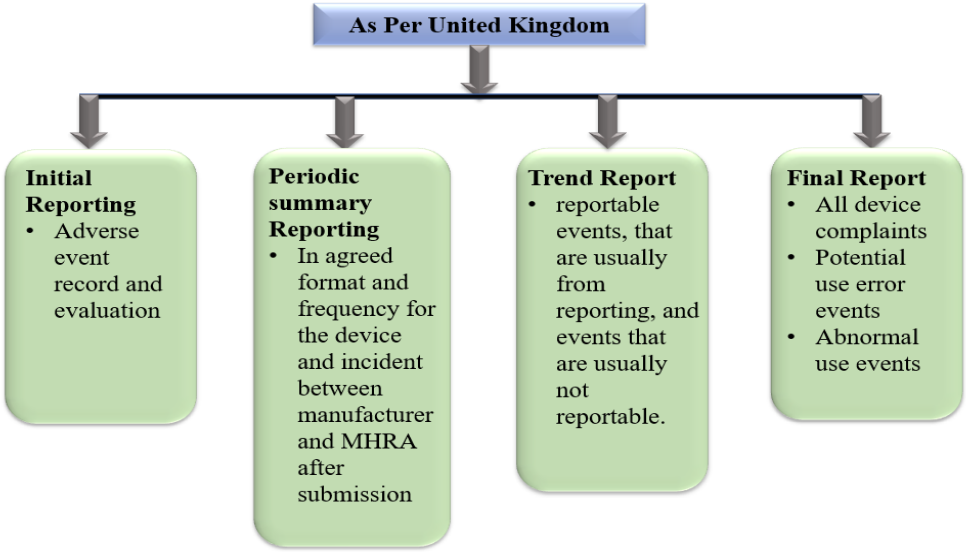

Figure 6. MHRA Reports

5. Vigilance reporting or vigilance exchange program (14, 15)

The National Competent Reporting System (NCRS) or surveillance exchange program is provided guidelines for how to manage the vigilance exchange of the two types of information.

- Confidential information
- Non-confidential information

The necessity for the surveillance exchange program is depends on the severity, unexpected nature of the incident, the most vulnerable type of population, the risk or benefit ratio, etc. The information exchanged includes events for which corrective action is required and can lead to serious risks for patients if not considered. GHTF has published NCRS forms, which can be used to exchange information directly with the NCRS Secretariat, which will help with proper global distribution. The producer report and NCRS must be distributed within 14 days of the producer notification of the event. (14)

In the United States, the FDA doesn't specify a vigilance exchange program as it a one of postmarked activities

The information dissemination to other NCAs are called NCARs in the UK. The statistics must be copied to the Commission and disclosed to other NCAs to help prevent recurrence of accidents, based on the results of the manufacturer's examination and the limitations of its consequences. The information should be released when the manufacturer has taken Field Safety Corrective Action (FSCA) or requested by the MHRA; The MHRA necessitates changes that have already been introduced to the FSCA, but corrective action has not yet been taken and is considered, although there is a severe risk to the health of the patient / user; and the manufacturer did not provide final report in a timely manner. (15)

6. Records

Records of each batch of a medical device must be kept. Delivers information of product, including supply, manufacturing, and other appropriate data. To sustenance MDR regulations, some written procedures for evaluating information regarding the ability to report an event, protocols to follow during investigations, any reports that are filed with the FDA regarding the MDR, etc. must be maintain by manufacturers. All history, incidents reported on each device, as well as actions taken, must be part of the log or logs. In the event of an adverse event, the records must be kept for 2 years or for a period corresponding to the expected useful life of that device. A detailed evaluation of event reports, user complaints, post-marketing clinical follow-up, etc. should be in records These must be kept throughout the life of the medical device. (16)

Establish a recognized procedure for an opinion system and its action meets the standards of a 'medical device quality management system' of UK manufacturers.

7. Enforcement action

The CDSCO (Central drug standard control organisation) should incorporate enforcement actions in the incident of regulatory non-compliance with regulations and must include a recovery system for the same. (17)

Any complaints regarding products with or without CE marking, examines the facilities of manufacturing for regulatory non-compliance investigate by MHRA and investigates the results of surveillance reports for the compliance within the regulation of UK medical devices regulation. A number of executive powers under the Consumer Protection Act of 1987, the Medical Device Regulations of 2002 and the General Product Safety Regulations of 2005 defined by the MHRA. (18)

8. Recall (19-22)

The manufacturer, supplier and customer can report complaints as quality defects when marketing a medical device. If a justification of product's defect complaint is not proper, it is considered as a quality system failure and product recall requires immediate corrective action. (19)

The MHRA guidelines describe recall as a Field Safety Corrective Action (FSCA) to decrease the risk of impairment to workers, patients or others or to decrease the incidence of the occurrence. The FSCA would include the following actions (20):

- Return of the medical device to the manufacturer
- Alteration of medical device
- Advice on using the device provide by the manufacturers.
- Replacement of medical device
- Device destruction

The manufacturer must send a Field Safety Notice (FSN) by appropriate means, such as an authorization receipt. The FSN itself should consist of the following elements (21):

- "Urgent Field Safety Notice" is the title on the notice itself, on the cover sheet if it is sent by post, and as the subject if it is sent by email or fax.
- Recipients: A strong statement about the intended receiver of the notice.
- A brief description of the medical device in question (model, lot or serial number)
- The reasons for the FSCA are described by a certain statement of fact.
- A clear risk associated description with the specific failure of the medical device and, where applicable, the comparable event that occurred, considering the relevant public.
- The suggested action that the FSN recipient must take.
- Limits by which the manufacturer and user should take action, if applicable
- Designated point of contact for the FSN recipient to use for additional data.

Classification for recall by USFDA based on its associated health risks which are as follows (22):

- Class I: where serious adverse health consequences or death are likely to occur.
- Class II: where medically reversible health consequences are likely to occur.
- Class III: where use or exposure to the harmful product is unlikely to cause adverse health significances.

Withdrawals are considered as urgent safety-related withdrawals for Class-I and class-II medical devices, though withdrawals are considered as routine non-safety withdrawals for Class-III medical devices.

To produce evidence for recognizing problems related to the use of medical devices to facilitate the development of safety devices is the main purpose of medical device surveillance.

9. Medical device tracking (23-24)

Tracking of Medical device as one of the activities of the post marketing surveillance of device tracking from the time of its manufacturer to the end user which is listed by USFDA.to locate the device in case of any defect or any problem with the device with the help of medical device monitoring. (23) According to FDA law, monitoring is required by some medical devices, such as implantable medical devices, life support medical devices, the failure of such medical devices will have serious consequences. Regulations applied to monitor medical devices came into effect on August 29, 1993 and can be found at 21 CFR part 8216.

The Adverse Incident Tracking System (AITS) must be followed in UK. according to the revised MHRA guidelines: in MHRA guidelines there are some classes of adverse events.

- Urgent in death
- Standard
- Information
- Other

A batch number is assigned to each medical device to facilitate the tracking process in India. When evaluating the link between the device and the adverse event, the manufacturer must consider the following details (24):

- health care experts' opinions
- similar events occur earlier

- Complaints trends
- Additional data held by the manufacturer

Difference in Medical device vigilance system of India, US and UK (25)

Table 1. Difference in Medical device vigilance system of India, US and UK (25)

Sr.no	Parameters	India	United States (US)	United Kingdom (UK)
1.	Name of regulatory authority	Central Drugs Standard Control Organisation	Food and Drug Administration	Medicines and Healthcare products Regulatory Agency
2.	Definition of medical device	10 device categories regulated as a drug	Include all instruments, materials, machine, appliances, in vitro diagnostic agents, implants, software and disinfectants	Excludes materials used for disinfection of medical devices
3.	Post marketing surveillance activities	Reporting of an Adverse event for importers complaint handling adverse event reporting process for distribution of records process for recall	Medical device tracking MDR event files, records, and written processes Complaint handling Recall process and seizures	Adverse event reporting FSCA and field safety notices Investigations Enforcement Post market experimental follow-up Records
4.	Medical device tracking	In labelling provisions, the lot number/batch number for device is mandatory for easy traceability	Have recognized tracking system since 1993	AITS established to investigate the failure modes of the device by assessment of user reports
5.	Who need to report AE	Manufacturers only	Manufacturers, importers, user facilities, users, distributors, and health professionals	Manufacturers, users, health professionals, authorized representatives, and MHRA
6.	Criteria for reporting	Event has occurred medical device's association with the event, Event led/might lead to death/ serious injury	Death or serious injury Device malfunctions User error Injury/illness requiring medical intervention	Event has occurred medical device's association with the event, Event led/might lead to death/serious injury
7.	Not-reportable incidents/events	User-detected insufficiencies Root cause of the adverse event is due to the patients' pre-existing condition Exceeded service life of device Probability of adverse event is satisfactory after risk assessment Side effects clearly identified in the manufacturer's labelling and documented in device master record	Manufacturers can apply for RAE, e.g., Erroneous information When other manufacturer makes the device	User-detected insufficiencies Root cause of the adverse event is due to the patients' pre-existing condition Exceeded service life of device Probability of adverse event is adequate after risk assessment Side effects clearly identified in the manufacturer's labelling and documented in device master record
8.	Reporting time frame	Unanticipated death or serious injury within 10 days All other reportable events not later than 30 elapsed calendar	Manufacture: death, serious injury, and malfunctions – 30 calendar days, and events requiring immediate remedial action – 5 working days User facility: death and serious	Serious public threat – 2 calendar days Death/serious deterioration – 10 elapsed calendar days other incidents – 30

		days	injury – 10 working days Distributors and importers: death, serious injury, and malfunction to manufacturer – 10 working days	elapsed calendar days After receiving user reports from MHRA, reporting 3 working days
9.	Types of report	Initial reporting Trend reporting Final reporting	30-day reports 5-day reports Baseline reporting Supplemental reporting Annual reports	Initial reporting of adverse events Final reports Periodic summary reporting Trend reporting
10.	Applicable forms	Adverse event reporting form	Form 3500 – online Form 3500A for manufacturers, importers, and distributors Form 3419 Form 3417 Form 3381	Manufacturer's incident report forms Online reporting for manufacturers by MORE
11.	Vigilance exchange	Not defined	NA	Yes
12.	Records	A mandatory specification for importers only	AE records Evaluation records for follow-up and inspection Investigation protocol Copies of test, laboratory reports, and service records	AE records Evaluation records Customer/user complaint record Records for products manufactured Records of distributors CAPA records
13.	Recall/FSCA	A mandatory specification for importers only	Manufacturers need to initiate recall	Manufacturers need to initiate recall
14.	Recall communication	NA	Telephone calls, telegrams, and mailgrams First class letters approved by FDA General public warning public warning through specialized news media	FSN approved by MHRA as per specified format within 48 hours of FSCA agreement in case of urgency, through telephone, fax, or by a visit

10. Conclusion

To analyse, examine and prevent the recurrence of adverse effects that occur with to the use of medical devices is the main purpose of materiovigilance. To ensure the safety of medical devices among device users in India MvPI is a good initiative. globally, medical devices are regulated by definite guidelines. reduction the risk associated with the use of medical devices is the main purpose of post-marketing surveillance. Valuable information that could prevent similar incidents in future by reporting adverse events. Due to the multiplicity and complexity of medical devices, it is essential in all countries to have the standard procedure for reporting incidents to the regulatory authorities (through the development of a national incident reporting system) and these requirements must be instantaneously applicable., it is necessary to promote incident reporting for the improvement of the efficiency of the medical device surveillance system.

Acknowledgements

We thank the all the members of Graduate School of Pharmacy, Gujarat Technological University for providing their informative suggestions.

Financial Disclosure statement: The authors received no specific funding for this work.

Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this article.

References

1. Hoda F, Verma R, Arshad M, Siddiqui AN, Khan MA, Akhtar M. Materiovigilance: Concept, structure and emerging perspective for patient's safety in India. Drug Res (Stuttg). 2020 Sep; 70(9):429-36.
2. Gupta SK. Medical Device regulations: A current perspective. J Young Pharm. 2016 Jan; 8(1):6-11.
3. Jefferys DB. The regulation of medical devices and the role of the medical device's agency. Br J Clin Pharmacol. 2001 Sep; 52(3):229-35.
4. Rani S, Singh K. Materiovigilance: an emerging discipline. Inter J Sci Res. 2018 June; 7(6):15-6.
5. Masurkar P. A need of better pharmacovigilance system in India. Asian J Pharm Clin Res. 2017 Jan; 10(1):22-4.
6. Materiovigilance Programme of India (MvPI) - Indian Pharmacopoeia Commission [Internet].IPC; 2020 Jul 22 [cited 2021 Jan 29]. Available from: http://ipc.gov.in/mandates/pvpi/materiovigilance-programme-of-india-mvpi.html
7. Kalaiselvan V, Kumar P, Mishra P, Singh GN. System of adverse drug reactions reporting: what, where, how, and whom to report? Indian J Crit Care Med. 2015 Sep; 19(9):564-6
8. GHTF. Comparison of the Device Adverse Reporting Systems in USA, Europe, Australia, Canada and Japan. Global Harmonization Task Force; 2002
9. Golder S, Wright K, Rodgers M. Failure or success of search strategies to identify adverse effects of medical

devices: a feasibility study using a systematic review. Syst Rev. 2014 Oct; 3(8):1-6
10. Kumar P, Kalaiselvan V, Kaur I, Thota P, Singh GN. Materiovigilance program of India (Mvpi): A step towards patient safety for medical devices. Eur J Bio and Pha Sci. 2016 Nov; 3(12):497-501.
11. Making medical device vigilance more effective. [Internet]. MHRA; 2007 [cited 2021 Feb 15]. Available from: http://www.mhra.gov.uk/NewsCentre/CON2033159
12. Judith A. Johnson. FDA regulation of medical device**.** Congressional Research Service; 2016
13. Pane J, Francisca RDC, Verhamme KMC, Orozco M, Viroux H, Rebollo I, et al. EU postmarket surveillance plans for medical devices. Pharmacoepidemiol Drug Saf. 2019 Sep; 28(9):1155-65.
14. Georgette Lalis. Medical Devices Post Market Surveillance: Global Guidance for Adverse Event Reporting for Medical Devices. Global Harmonization Task Force; 2006
15. Stout L. GHTF SG1 - Definition of the Term Medical Device. J Corp Law. 2014 Sep; 1(5):526-44.
16. Shukla S, Gupta M, Pandit S, Thomson M, Shivhare A, Kalaiselvan V. Implementation of adverse event reporting for medical devices, India. Bull World Health Organ. 2020 Mar; 98(3):206-11.
17. U.S. Food & Drug Administration. Recalls, Collections and Removals (Devices) [Internet]. FDA; 2020 Sept 29 [cited 2021 Feb 13]. Available from: https://www.fda.gov/medical-devices/postmarket-requirements-devices/recalls-corrections-and-removals-devices
18. USFDA. Regulatory procedures manual, chapter 7 recall procedures. 2020; 8:61-67
19. Medicine and healthcare products regulatory agency. Medical devices: guidance for manufacturer on vigilance [Internet]. Gov.uk [cited 2021 Feb 22]. Available from: https://www.gov.uk/government/collections/medical-devices-guidance-for-manufacturers-on-vigilance
20. The Medical Devices Regulations 2002 [Internet]. legislation.gov.uk; 2002 [cited 2021 Feb 22]. Available from: https://www.legislation.gov.uk/uksi/2002/618/contents/made
21. USFDA. Medical Device Tracking Guidance for Industry and Food and Drug Administration Staff. Center for Device and Radiological Health; 2014
22. USFDA. Medical device tracking [Internet]. FDA; 2018 Sept 27 [cited 2021 Mar 29]. Available from: https://www.fda.gov/medical-devices/postmarket-requirements-devices/medical-device-tracking
23. Terms of Reference Research Associates – Materiovigilance Program of India (MvPI). National Health Systems Resource Centre, MoHFW, Government of India [Internet]. [cited 2021 Feb 25]. Available from: http://nhsrcindia.org/archive/terms-reference-research-associates-%E2%80%93-materiovigilance-program-india-mvpi
24. Postmarket 522 Surveillance Studies. [Internet]. HealthData.gov; 2021 [cited 2021 Jan 29]. Available from: https://healthdata.gov/dataset/522-postmarket-surveillance-studies-1
25. Chauhan P, Zarreen A, Iqubal MK. Current status of materiovigilance globally- an utter overview with clinical case perusal. Int J Pharm Pharm Sci. 2019 Sep; 11(10):1-7