RESEARCH ARTICLE

Comparative Materiovigilance Program for US, Europe, Japan, India and Proposed Reporting Mechanism for Indian Scenario

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Received: 20th March, 2023; Revised: 11th June, 2023; Accepted: 28th August, 2023; Available Online: 25th September, 2023

ABSTRACT

Medical devices are thought to be a blessing for the healthcare system because they are tools that can save lives. Apart from therapeutic potential, these devices have lot of negative side effects. It took a strong cohort attentive system to control such negative impacts. As a result, materiovigilance was introduced. Materiovigilance is the investigation and monitoring of incidents brought on by the use of medical devices. It controls adverse events (AE) and brings about international harmony. These goals are kept in mind when the principles, viewpoints, and materiovigilance techniques in the USA, Europe, China, Japan, Australia, Canada, and India are contrasted. It is crucial to make this comparison to comprehend the shortcomings of the current regulatory frameworks in the nations described above. Additionally, it will give the regulatory authorities a complete picture so they can alter any existing legislation as necessary. In the present study, an ideal proposed model of medical devices for its approval has been explained easily.

Keywords: Materiovigilance, Medical device regulations, Medical devices.

International Journal of Pharmaceutical Quality Assurance (2023); DOI: 10.25258/ijpqa.14.3.12

How to cite this article: Teli MS, Jhawat V. Comparative Materiovigilance Program for US, Europe, Japan, India and Proposed Reporting Mechanism for Indian Scenario. International Journal of Pharmaceutical Quality Assurance. 2023;14(3):534-540.

Source of support: Nil.

Conflict of interest: None

INTRODUCTION

As per the FDA classification, medical devices encompass a broad range of items such as machinery, equipment, instruments, implants, or components used *in-vitro*. These are employed in the context of managing, mitigating, diagnosing, or averting specific medical conditions or diseases. Medical gadgets are not dependent on humans, yet it is anticipated that they will affect both human and animal body structure and function when metabolized to achieve any of its primary expected outcomes.[1] The use of medical equipment has dramatically increased. As a result, it is essential to guarantee their effectiveness and quality. However, there are differences in device quality, and even the best gadget could malfunction in a clinical setting. Additionally, these technologies might result in safety problems that unintentionally hurt the patients. Therefore, post-marketing surveillance is crucial in resolving these problems because it aids in assessing the effectiveness of gadgets and concentrates on their safety.[2] In addition to post-marketing surveillance, medical device harmonization is essential. The primary goal of harmonization is to promote the integration of regulatory workflow to ensure the quality, safety, and efficacy of medical devices. This will increase global demand and spur scientific innovation.[3] Harmonization is a crucial initiative that shortens the time needed for these medical devices to be marketed and helps to lower the cost involved in doing so. In addition, it tries to improve the device's effectiveness and safety, restoring users' faith and confidence in it.

Pharmacovigilance (PV), a specialized field within pharmaceutical sciences, is primarily concerned with identifying, evaluating, monitoring, and effectively handling adverse events (AE) or adverse drug reactions (ADR) associated with particular pharmaceutical products. Its central mission revolves around the comprehensive management of these drug-related incidents. To track unfavorable events involving medical equipment, the IMDRAF was founded in 2011. It was designed to hasten the convergence and harmonization of medical device regulation across borders. The establishment of materiovigilance was made possible by this international body, which was made up of ten nations, including Japan, China, India, the EU, the USA, and South Korea (MV).[4] MV involves the examination and ongoing observation of incidents that could be attributed to the utilization of medical devices. Given that all such equipment inherently carries some level of risk and the potential for complications in specific scenarios, MV serves the purpose of identifying adverse events associated with these medical devices. Through vigilant monitoring, this practice not only facilitates the removal of hazardous products

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from the market but also enables companies to address and rectify any underlying flaws. This would raise the caliber of the gadgets, ensuring patient and consumer safety.[5] Guidelines and rules can differ between nations.

In 1992, a collaborative effort known as the Global Harmonization Task Force (GHTF) was established, uniting five nations: the US, Canada, Japan, Europe, and Australia. The primary objective of this alliance was to foster uniformity in the regulatory frameworks governing medical devices at the national level, with a shared emphasis on ensuring both efficacy and safety.[6] While individual countries may have distinct definitions for medical devices, the GHTF defines medical devices as tool, implement, instrument, calibrator, substance, or software designed for specific purposes within the realm of human healthcare by its manufacturer. This included systems for maintaining life, preventing and controlling sickness and injury, diagnosing and monitoring those conditions, and cleaning and sanitizing medical equipment. Furthermore, it's worth noting that the therapeutic goods administration (TGA) has expanded its definition of medical devices to encompass items such as homes, tampons, hospitals, and commercial-grade disinfectants. The MHRA has, somewhat unexpectedly, not included certain disinfection components used for medical equipment within its regulatory scope. Interestingly, India has traditionally categorized medical supplies as "drugs." It's interesting to note that India continues to view medical devices as "drugs." Most nations had very few regulations governing medical devices, and those that did exist were quite tight to prevent the use of subpar tools. So, considering this overall scenario, a strong demand to create efficient medical device legislation regulations was created so that their effectiveness, safety, and efficiency could be evaluated. Since the 1980s, the environment for medical device regulation has significantly transformed. To lower challenges associated with regulatory approvals and speed up access to medical equipment, it was also necessary for nations or regions to harmonize their medical equipment legislation. Comparisons could aid in identifying the gaps in worldwide regulatory procedures and give regulatory agencies a vision for how to change the law to create a safer and more effective medical device.[3]

There are various principal purposes of materiovigilance which include lowering the frequency of incidents help to improve the patients' and others' health and safety, assessing the GHTF suggested framework for the Indian medical device vigilance system and its implications, bringing about improvements in the equipment's utilisation and productivity, to establish a national framework for assessing patient safety. Several key actions should be taken to assess the balance between the advantages and potential risks associated with medical devices. First, it's crucial to disseminate safety information concerning the use of these devices to all pertinent stakeholders. Second, establishing a national hub for materiovigilance operations can significantly reduce risks. Third, fostering collaboration with international organizations and other healthcare entities is essential for effective information sharing and data management through the National Coordination Centre. Lastly, raising awareness among all relevant parties about the significance and necessity of reporting medical device adverse events (MDAE) is of paramount importance.[7]

Medical device classification systems vary widely around the globe; hence it is important to assist the process of global harmonization while classifying the equipment. Table 1 compares the global classification of medical equipment.[8]

METHODOLOGY

We thoroughly searched various platforms, including Google, Google Scholar, PubMed, and ScienceDirect. Our search was focused on publications, review articles, research papers, and events about medical devices and their associated AE. We employed keywords such as 'medical device,' 'materiovigilance,' and 'AE related to medical devices' to identify relevant content. Additionally, we sought out specific case studies related to medical devices as part of our research. A comparison of regulatory approval processes between US, Japan, India was searched and a comparison was done.

Regulatory Requirements for Different Countries

United states

Medical devices in the US comes under the regulatory purview of the United States FDA, commonly referred to as the US FDA. A device can be legally placed into the market if the FDA has approved it and determined it is safe and suitable for its intended use. It utilizes the "least burdensome approach," which means that manufacturers are required to furnish information essential to prove the safety and effectiveness of their devices, without excessive demands. These devices are categorized into three groups, each reflecting a different level of risk, as detailed in Table 1. There are different pathways for the acceptance of devices in the US.

- *Pre-market notification (PMN) pathways*

This method is used to regulate devices that fall under class I and some (about 25%) that fall under class II. When a device seeks clearance through this route, the manufacturer must show that it closely resembles the predicate device, per Code of Federal Regulation (Title 21, Section 807) requirements. This process doesn't necessitate the submission of clinical data, making it quicker and more cost-effective compared to the pre-market approval (PMA) route. This efficiency has led to it colloquially called the "fast track approval process." It's important to note that "substantial equivalence" doesn't imply that the new device must be identical to the predicate device; instead, it signifies a close resemblance in key aspects. In actuality, it simply implies that a new device's "intended use" and "technical attributes" should be identical to those of the predicate device.

- *PMA pathway*

The PMA pathway is pursued to determine the safety and effectiveness of devices. It is in charge of regulating all class III devices and the majority (75%) of class II devices. It only applies to devices that are different from the predicate devices.

Table 1: Medical devices classification

Country	*Class I*	*Class II*	*Class III*	*Class IV*
US	General controls E.g.: Gauzes toothbrushes.	Specific controls. E.g.: Sutures, needle.	Pre-market approval. Pacemaker	…
EU	Low risk. E.g.: Gloves, dressings.	Low-medium risk. E.g.: Surgical blades,	Medium-high risk. E.g.: Ventilators,	High risk. E.g.: Pacemakers, stent
Japan	Extremely low risk. E.g.: X-ray film	Low-risk, e.g.: electronic endoscope.	Moderate risk. E.g.: Bone prosthesis	High risk. E.g.: Pacemakers, grafts
India	Class A (low risk), E.g.: Surgical dressings, sutures, swab	Class B (low-moderate risk), E.g.: fiberoptic oximeter catheter.	Class C (moderate-high risk) E.g.: Uterine balloon therapy	Class D (High risk) E.g.: Heart valve.

As a result, these devices are known as "*De Novo* Devices." Clinical studies are included here, providing additional information necessary for creating, accepting, and using technologies. This pathway comprises four distinct stages integral to the oversight of medical devices. These stages are as follows:

- Pre-Investigational Device Exemption/Pre-Clinical Evaluation
- Clinical Testing
- PMA Submission
- Post-Marketing Surveillance
- *Humanitarian device exemption (HDE) pathway*

HDE encompasses devices designed to treat or diagnose uncommon diseases, specifically those affecting fewer than 4,000 individuals annually. This application's format and content are comparable to the PMA application's, except for the effectiveness requirement.[7]

Europe

The European Union (EU) regulations are being adhered to to approve medical devices. There are 50 NB across all of Europe, and they are private businesses that enter into agreements with medical device manufacturers and collect fees from them for certification of their products. A NB's primary responsibility is to thoroughly examine the application and adhere to EC regulations. It will provide the medical gadgets with a CE mark if all the supervision requirements are completed. Once medical devices receive CE marking approval, there is no need for any additional assessments or evaluations. However, a brand-new law from 2010 established certain tight guidelines for the sanction of medical device considering similar properties of new medical devices and predicate devices. The following stages demonstrate how medical device approval is decentralized in Europe.

Step 1: Identifying the type of equipment and then properly including it in one of the classes. The appropriate evaluation approach is then picked next.

Step 2: QMS implementation

Step 3: Creation of dossier outlining which is a stringent legal need as well as another necessary compliance.

Step 4: Then throughout Europe, a designated representative is chosen. On the label of the medical device, the representative's name and address should be prominently displayed.

Step 5: Preparation of Europe's declaration of conformity

Step 6: It is necessary to hire a notified body to conduct a legal audit of the suppliers and manufacturers.

It is then created following the specifications, and the dossier filing is completed.

Step 7: The manufacturer receives the European CE certificate after the aforementioned requirements are verified.

Step 8: The medical device has CE written on it and is prepared for lawful marketing.

Japan

In Japan, medical device regulation combines elements from European and American regulatory approaches. The procedures for approving and reviewing medical devices are overseen by the Pharmaceutical Medical Device Act (PMDA). Ensuring the efficiency, security, and calibre of medical devices, medications, and cellular therapy items is also referred to. QA system, and licenses required for the registration of Japanese medical items are prohibited by this Act.[9-11] A few prominent characteristics of this act are, that each piece of medical software is governed separately, the producers must first register to proceed. The quality management system (QMS) as a whole has been streamlined. The marketing authorization holder is the target of the QMS inspection. Considering the risk levels, medical devices has been grouped in to three classes. Class-1 devices are considered to have an exceptionally low risk, and for these devices, a marketing requirement called "Todokeda" is sufficient, indicating that formal certification for device approval is not necessary. On the other hand, Class 2 and 3 devices must comply with specific certification requirements. A medical device application referred to as "Ninsho" is submitted to seek approval for these devices. MHLW acts as the registering authority and evaluates these applications. For Class 2 and 3 devices, assessment and evaluation are carried out by the PMDA, with ultimate approval from the MHLW. These submission applications are termed "Shonin." On July 31, 2017, the MHLW unveiled a fresh regulatory framework known as the "fast-break" strategy to hasten patient access to breakthrough medical devices. This initiative aims to streamline the collection of essential data required for device approval in Japan. It is important to note that the "fast-break" plan is specifically designed for novel medical devices.[12]

India

In India, medical device performance, quality, and safety are governed by the D &C Acts, 1940, and Rules, 1945. For a very long time, India lacked a proper method to track the unfavourable outcomes related to the use of medical devices. In collaboration with the Drugs Technical Advisory Board, the Indian government recently introduced the Medical

Equipment Rules in 2017. These rules are aimed at regulating the import, production, and sales, as well as establishing a proper distribution chain for medical products and devices throughout the country. In response to the imperative need for enhanced safety monitoring of medical devices in India, the Pharmacovigilance Programme of India (PvPI) plays a pivotal role. Within this framework, the Sri Tirunal Institute for Medical Sciences and Technology (SCTIMST) was designated as the National Coordinating Center (NCC) for the launch of the Materiovigilance Programme of India (MvPI) on July 6, 2015. The significance and necessity of MvPI are growing every day because of the rising number of medical devices that are failing as well as numerous other occurrences of device-related adverse events that result in problems or, in some extreme circumstances, patient death. Subsequently, beginning in 2018, the Indian Pharma Commission (IPC) took on the role of being the National Coordinating Center (NCC) for both PvPI and MvPI. One of the unique challenges faced by MvPI is that infrastructure and capacity building differ in nature compared to the tools, data collection, and assessment procedures employed for drugs. Recognizing this, it's important to emphasize that successful implementation of MvPI necessitates not only collaboration across various departments but also underscores the crucial role played by biomedical engineering departments within hospitals and other institutions on an international scale. Consequently, the authority to serve as medical device adverse event centers has been granted to Institutions with Biomedical/Clinical Engineering Departments (BMEDs) (MDMCs). Additionally, if they are still connected to BMED, preference is given to other departments as well. BMED's involvement is crucial because the majority of medical devices are created using engineering technology.[13,14]

The MvPI aims at

- Establishing a national strategy for assessing patient safety
- Examining the medical device's benefit-risk ratio
- Generating evidence-based information for medical equipment linked to unfavourable incidents
- Sharing safety-related information with multiple industry stakeholders
- Cooperating with international organisations and other healthcare organisations to handle data and exchange information

An Indian regulatory body (MvPI) is steadily gaining steam to match global regulation with its post-marketing surveillance. Unlike the EU and the US, where there are precise criteria for their post-marketing surveillance programme device safety, India does not have any.

We need to create tools and establish guidelines for identifying signals, and it's essential to validate the process of assessing causality. Increased grassroots participation is necessary for the MvPI to succeed. MvPI needs to be more widely known among the public and the healthcare profession for this to happen. Potential reporting hurdles such as ignorance of reporting procedures, a lack of knowledge about how to report, fear of reputational damage, and medicolegal concerns need to be resolved.[15]

The National Regulatory Agency or the Medical Council of India should consider incorporating MvPI as a mandatory learning requirement for license renewal. This would encourage a culture of increased reporting of MDAE within hospital registries and the inclusion of information about implanted devices on patients' outpatient department cards.[16,17] This initiative is a result of collaboration with healthcare organizations and corporate hospitals. Additionally, there is a need to assess the capability of clinicians to suspect when adverse events may be linked to the use of a medical instruments/devices. The comparison of various required parameters of all countries are presented in Table 2.

Proposed Model

Medical devices are grouped considering the risk levels like class A, B C D with the lowest risk to the highest risk. The SLA oversees the production of class A and B medical devices, while the CLA, also known as the CDSCO, regulates the production of class C and D medical devices. Further, the CDSCO regulates the import and clinical investigation of all medical devices while the SLA regulates sales of medical instruments/devices. In terms of the process, products, and performances and to increase the level of standardization and quality of the product, standards should gradually expand. It may involve, enabling the creation of goods that are ready for the market from the design phase itself, and to ensure quicker approvals, compliance should be ensured with the necessary regulatory standards during the research phase. Through the research and design phases of product development, the standards-setting organisation will mentor researchers, innovators, and entrepreneurs and prepare them for the testing phases.

In case of adverse event reporting, there are various ways to report by the importers, manufacturers, or distributors. The regulation should be updated for the proposed model so that end users can also report the adverse event on the website of the approval process for which details should be given on finished products. Post-marketing surveillance should be carried out by the manufacturers by collecting data from importers and distributors. The timeline of adverse event reporting will be immediate reporting as soon as possible to avoid the risk to the products and to maintain quality, safety, and efficacy. There should be one platform nominated by the competent authority to easily access the adverse event by manufacturers. In device tracking, medical devices need to establish sales recording system which should include production lot number, validity, manufacturer name, contact details, and number of relevant licensing documents.

Each prescription should be attached to the materiovigilance AE reporting form in hard copy and placed at each distribution center and AE reported if any by the patient submitted to the local FDA office. The form should be in a bilingual language i.e., in English as well as in the local language. Each local SLA/zonal state FDA office should select a district materiovigilance

Table 2: Comparative requirements for all countries

Requirements	*USA*	*Europe*	*Japan*	*India*
Classification of medical devices	Class I, II, III	Class I , IIa, IIIb, III	General class I Specified control class II controlled class II Highly controlled-class III Highly controlled -class IV high risk	Class A (low risk), Class B (Low moderate risk), Class C (moderate-high risk) Class D
Procedure for market authorization	Pre-market notification market approval	Annex II-VII of the MDD	MAH DMHA	Drugs Controller General of India (DCGI)
Registration of economic operators and devices	Register annually with the FDA	European EUDAMED	Pharmaceuticals and Medical Devices Agency (PMDA)	Importers and distributors
Involvement of government	Direct involvement of government FDA	national competent authority	Third-party certification, The pharmaceutical and medical device agency	National competent authority
Marking of medical devices	no official mark for FDA-approved devices	CE mark on the product	No official marking required	CE mark required
Standards for medical devices	FDA; Centre for devices and radiological health	European committee for standardization	Translated international standards or other recognized standards like IEC or ISO	CDSCO released Indian Medical Device Rules, 2017
Decision making	Decision to allow a device to the market is made by FDA	national competent authority	PMDA, MHLAW	CDSCO authority
Authorization status of products	No mark on the product to identify an approved device	Advice that has successfully gone through the conformity assessment procedure	No official marking required	CE mark required
Device Tracking	As a form of post-marketing monitoring, device tracking is used. Depending on the device's classification, manufacturers are obligated to furnish information within either a 3-day or 10-day timeframe.	Through the Adverse Incident Tracking System, the EMA oversees device tracking (AITS). The manufacturer or authorized representative is responsible for tracking incident reports.	Reports for the items are produced by sponsors using information gathered from medical professionals, clinical trials, and published studies, such as international and local observational research or experiences from registries.	Lot/batch numbers must be displayed on a medical device's label.
Adverse event reporting	Under MDR regulations, manufacturers and importers have a responsibility to promptly report any incidents involving serious injury or death within 30 days from the time they become aware of these occurrences. Manufacturers are obligated to disclose faults that have been discovered within 30 days.	At post-marketing surveillance, manufacturers are accountable for disclosing concerns related to the medical equipment.	The Marketing Authorization Holder (MAH) is obliged to notify the MHLW about serious ADR within 15 days. However, for newly introduced drugs on the market for less than 2 years, this reporting period extends to 30 days.	Adverse events can be reported by a range of stakeholders, including the manufacturers, importers, distributor, even customers.
Timeline of reporting	To report death=30 days, to report injuries and malfunction=5days	To report death=10 days to Competent Authorities	The mandatory reporting period for AEs is 15 days (in some situations, 30 days).	Immediate reporting ASAP
The time frame for approval	To FDA to process PMA approvals	210 days are laid down for the scientific opinion	3-4 months	6-9 months

nodal officer and a weekly report should be sent to the national coordination center for trend analysis and the national regulatory authority. This will facilitate a successful device recall and raise awareness of potential safety measures.

A third party who is independent of any Government affairs should be appointed to keep strict vigilance on the adverse effects of the devices in the market in coordination with distributors and hospitals and customer follow-up should be

Table 3: Requirements of the proposed model

Requirements	*Proposed model*
Finished product mark	Use of Unique Device Identification (UDI) system
The time frame for approval	As early as possible
Adverse event reporting	End users can also report on the website giving the details on finished products
Post-marketing surveillance	By manufacturers
Timeline of reporting	immediate reporting
Device tracking	Should establish a sales recording system
Standards for medical devices	Separate team for standardization

taken. There are various advantages which include, the AER form being in the local language to allow for the collection of first-hand information, More than 60% population lives in rural India so offline reporting is also suitable.

Furthermore, there is a push for the implementation of the unique device identification (UDI) system, which serves as a method to distinguish medical devices. This system relies on a universally accepted standard for device identification and coding, employing various sets of the combinations characters including numeric as well as alphanumeric. Its primary purpose is to facilitate precise market identification of individual medical devices.

It's designed to establish a unified, globally consistent means of positively identifying medical devices from the point of distribution to their usage. This entails the mandatory inclusion of a globally unique device identifier on device labels, which is based on an established standard.

Unique Device Identifier - Device Identifier (UDI-DI)

The device identifier within the UDI functions as a dual-purpose component. It serves as both the "access key" and a unique alphanumeric or numeric code that is specific to a particular model of a medical device. This unchanging section of the UDI is essential in specifying the precise product and packaging configuration for a manufacturer.

Unique Device Identifier - Production Identifier (UDI-PI)

Manufacturer Identifies within UDI is a numerical or alphanumeric code used to identify the unit of device production when specific details are included on the device's package label. This identifier is crucial for the traceability of medical products derived from human sources. The various kinds of PI contain

- Lot
- Serial Number
- Expiry Date
- Manufacturing date
- Software version
- The Distinct Identification Code

Unique Device Identification Database (UDID)

UDID system serves as the authoritative source for obtaining device identification information. Within the UDID framework, there's the Central Medical Device Master Database, which holds all the essential data for device identification within the jurisdiction. It is essential for informing manufacturers of data quality problems, monitoring data quality repairs and improvements, and managing submission responses.

One of the significant advantages of the unique device identification system is that it empowers medical service providers to efficiently verify if the medical devices present in the specific facility is subject to recall. This enables them to swiftly remove any affected devices from use. With UDI in place, there's no more guesswork involved. Hospitals no longer need to speculate about which manufacturer supplied the devices in recall period. Instead, of this the firm may have option to scan the barcode and get the information regarding the recall of medical devices.

Laws are put in place to reduce the likelihood of any AE related associated with utilization of medical devices. The overarching goal is to enhance the protection of patients, healthcare professionals, and the broader community in terms of health and safety. Considering the current state of healthcare systems worldwide, it becomes imperative to place a strong emphasis on safeguarding the well-being of patients. Monitoring medical devices is equally crucial as monitoring pharmaceuticals to ensure the safety of patients. The program for medical device surveillance Additionally serves as a tool for raising awareness of reporting adverse occurrences connected to medical devices among patients, healthcare providers, and others. Keeping an eye on manufacturers, whether or not they are addressing the problems, will also be beneficial. Studying the negative consequences of medical technologies will be a very useful tool for public health. Making reporting mandatory for medical device makers is one of this program's long-term objectives. The requirements of the proposed model are presented in Table 3.

CONCLUSION

Establishing worldwide regulations for the approval of medical devices is crucial. It's a vital step to guarantee their quality, safety, effectiveness, and performance before they can be introduced to the market. This robust regulatory framework serves as a safeguard, aiming to prevent potential issues while simultaneously enhancing and sustaining public health standards. Ultimately, it plays a pivotal role in instilling trust and confidence in both the medical device itself and the manufacturer among consumers. Devices are divided into multiple classes according to their level of risk, and each class has its own set of regulatory requirements for device clearance that vary from place to region. Manufacturers strive to produce and market safe, efficient, and high-quality medical devices, aiming to deliver the best products to the public. However, it's essential to acknowledge that various regions have distinct regulatory procedures, application fees,

and approval timelines. Despite these variations, the objective remains consistent ensuring the availability of top-notch devices to benefit the public. An ideal proposal must include less time for approval and should include the Approved product mark on the finished product. For standardization, one team should be appointed, and post-marketing surveillance will be done by manufacturers.

REFERENCES

1. U.S. Food and Drug Administration (2018). https://www.fda.gov/industry/regulated-products/medical-device-overview. Accessed 22 February 2021
2. Shukla S, Gupta M, Pandit S, Thomson M, Shivhare A, Kalaiselvan V, Singh GN. Implementation of adverse event reporting for medical devices, India. Bulletin of the World Health Organization. 2020 Mar 1;98(3):206.
3. Joshi D, Sharma I, Gupta S, Singh TG, Dhiman S, Prashar A, Gulati M, Kumar B, Vishwas S, Chellappan DK, Gupta G. A global comparison of implementation and effectiveness of materiovigilance program: overview of regulations. Environmental Science and Pollution Research. 2021 Nov;28(42):59608-29.
4. Yoon C, Nam KC, Lee YK, Kang Y, Choi SJ, Shin HM, Jang H, Kim JK, Kwon BS, Ishikawa H, Woo E. Differences in perspectives of medical device adverse events: observational results in training program using virtual cases. Journal of Korean medical science. 2019 Oct 14;34(39).
5. Kumar P, Kalaiselvan V, Kaur I, Thota P, Singh GN. Materiovigilance programme of India (MVPI): A step towards patient safety for medical devices. Eur J Biomed Pharm Sci. 2016 Nov;12:497-501.
6. Junnuthula V, Kolimi P, Nyavanandi D, Sampathi S, Vora LK, Dyawanapelly S. Polymeric Micelles for Breast Cancer Therapy: Recent Updates, Clinical Translation and Regulatory Considerations. Pharmaceutics. 2022 Sep 3;14(9):1860.
7. Chauhan PR, Zarreen AA, Iqubal MK. Current status of materiovigilance globally-an utter overview with clinical case perusal. Int J Pharm Pharm Sci. 2019 Sep;11(10):1-8.
8. Manu M, Anand G. A review of medical device regulations in India, comparison with European Union and way-ahead. Perspectives in Clinical Research. 2022 Jan;13(1):3.
9. Dave V, Yadav S, Gulati B, Gupta N,Yadav R (2018) Current scenario of regulation and monitoring of medical devices in global realms of world. Asian Hospital & Healthcare Management.
10. Pacific Bridge Medical (2018). Japan MHLW & PMDA medical device and pharmaceutical regulations
11. Saifuddin PK, Tandon M, Kalaiselvan V, Suroy B, Pattanshetti V, Prakash A, Medhi B. Materiovigilance Programme of India: Current status and way forward. Indian Journal of Pharmacology. 2022 May;54(3):221.
12. Kramer DB, Tan YT, Sato C, Kesselheim AS. Postmarket surveillance of medical devices: a comparison of strategies in the US, EU, Japan, and China. PLoS medicine. 2013 Sep 24;10(9):e1001519.
13. Hoda F, Verma R, Arshad M, Siddiqui AN, Khan MA, Akhtar M, Najmi AK. Materiovigilance: concept, structure and emerging perspective for patient's safety in India. Drug Research. 2020 Sep;70(09):429-36.
14. Gupta P, Janodia MD, Jagadish PC, Udupa N. Medical device vigilance systems: India, US, UK, and Australia. Medical Devices (Auckland, NZ). 2010;3:67.
15. Sarkar A, Sodha SJ, Junnuthula V, Kolimi P, Dyawanapelly S. Novel and investigational therapies for wet and dry age-related macular degeneration. Drug Discovery Today. 2022 Aug 1;27(8):2322-32.
16. Ingale MH, Tayade MC, Patil YP, Salunkhe R. Data Integrity Violations in the Pharmaceutical Industry and Regulatory Measures. International Journal of Pharmaceutical Quality Assurance. 2023;14(2):416-420.
17. Kanda A, Mazumder A, Das S, Prabhakar V, Singh T, Kumari S, Mishra A. Regulation of Autophagy in Neurodegenerative Diseases: A Brief Review on Autophagy Therapy for Neurodegenerative Diseases. International Journal of Drug Delivery Technology. 2023;13(1):423-433.