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ADVERSE EVENT REPORTING FOR MEDICAL DEVICES: A COMPARISON OF PROCESSES IN INDIA AND THE USA

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ABSTRACT

Medical devices are essential in modern healthcare, facilitating patient care through diagnosis, treatment, and monitoring. However, their widespread use is also associated with an increased incidence of adverse events. Regulatory frameworks like the FDA in the USA and the Materiovigilance Programme of India (MvPI) aim to improve the safety of medical devices through proper reporting of adverse events and regulation of their manufacture, import, and use. The FDA has a comprehensive post-market surveillance system compared to India's MvPI. Launched in 2015, the MvPI is still evolving as an effective monitoring framework and focuses on adverse event reporting and analysis. The MvPI has established 451 Medical Device Adverse Event Monitoring Centres nationwide, and the government introduced the Medical Devices Rules in 2017 for better regulation. Both countries encourage the reporting of adverse events by healthcare professionals, manufacturers, and consumers to ensure timely interventions. However, the MAUDE (Manufacturer and User Facility Device Experience) database provided by the FDA makes data regarding medical device adverse events more accessible to the public and healthcare professionals.

INTRODUCTION

Medical devices play a pivotal role in modern healthcare, facilitating diagnosis, treatment and monitoring various medical conditions. Their importance lies in enhancing patient care and improving treatment efficacy, thereby significantly contributing to the overall quality of healthcare delivery.

WHO defines medical device as "any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination for a medical purpose".[1] They include a spectrum ranging from basic materials like cotton gauzes to sophisticated software utilized in advanced medical equipment.

With the widespread use of medical devices of diverse range, the prevalence of adverse events linked to them has also increased. An analysis of data by International Consortium of Investigative Journalists found that more than 1.7 million injuries, including nearly 83000 deaths, were potentially linked to medical devices in USA between the years 2008 and 2018.[2]

Since the use and market size of medical devices is increasing day by day, it is important to tighten the regulations of medical devices and improve their post marketing surveillance.

Evolution of Materiovigilance globally and in India

The Food and Drug Administration (FDA) played a pioneering role as the first regulatory authority to establish rules governing the regulation of medical devices. The Medical Device Amendments to the Food, Drug, and Cosmetic Act of 1976 introduced a risk-based classification system for medical devices and established the regulatory pathways for new medical devices. The 1990 Safe Medical Devices Act refined post-market surveillance practices, enhancing safety protocols for medical devices.[3] Following the lead of the FDA, other countries such as the European Union (EU), Australia, and Canada implemented their own regulatory frameworks to govern the manufacture, sale, and use of medical devices.

In 1993, five countries—EU, USA, Japan, Canada, and Australia—joined forces to create the Global Harmonization Task Force (GHTF), aimed at bringing uniformity within regulatory frameworks concerning medical devices. Subsequently, in 2011, the International Medical Device Regulators Forum (IMDRF) was established with the objective of accelerating the harmonization of medical device surveillance practices across nations. Comprising ten member countries, including India, the IMDRF represented a significant step towards international cooperation in standardizing regulatory approaches to medical devices.[4]

India lacked a dedicated regulatory framework for the oversight of medical devices for an extended period. In the past, medical devices were regulated under the Drug and Cosmetic Act of 1940, where they were grouped together with pharmaceuticals, resulting in regulatory inefficiencies and challenges in ensuring patient safety.[5] Numerous incidents have been reported concerning the harm caused by medical devices, such as instances involving infant fatalities due to short circuits in incubators and cases where toxic chemicals were released into the bloodstream from hip prostheses.[6-9]

In response to these challenges, the Materiovigilance Programme of India (MvPI) was launched on July 6, 2015, by the Drug Controller General at the Indian Pharmacopoeia Commission (IPC), at Ghaziabad. The objective of MvPI was to systematically document, analyze, and report adverse events linked to medical devices, thus improving patient safety and regulatory supervision in the country.

Under the framework of MvPI, the Indian Pharmacopoeia Commission serves as the National Coordination Centre and Sree Chitra Tirunal Institute for Medical Sciences & Technology (SCTIMST) acts as the National Collaboration Centre. Technical support is provided by National Health System Resource Centre (NHSRC), New Delhi. Central Drugs Standards Control Organization (CDSCO), New Delhi functions as the National Regulator.

MvPI aims to methodically collect data on adverse events linked to medical devices and conduct thorough scientific analysis to inform regulatory decisions and recommendations regarding their safe usage in India. The program focuses on monitoring adverse events associated with medical devices, promoting awareness among healthcare professionals about the significance of reporting such incidents, and evaluating the risk-to-benefit ratio of medical devices.[10]

Medical Device Adverse Event Monitoring Centres (MDMCs) have been established nationwide to promote program awareness and improve reporting standards. Within the framework of MvPI, currently a total of 451 MDMCs have been designated across the country for the voluntary reporting of adverse events linked to medical device usage.[11] **(Figure 1)**

Later, the Government of India, in collaboration with the Drugs Technical Advisory Board, introduced the Medical Devices Rules, 2017, on January 31, 2017, which became effective from January 1, 2018. It aims to regulate the import, manufacturing, sales, and distribution of medical devices.[12]

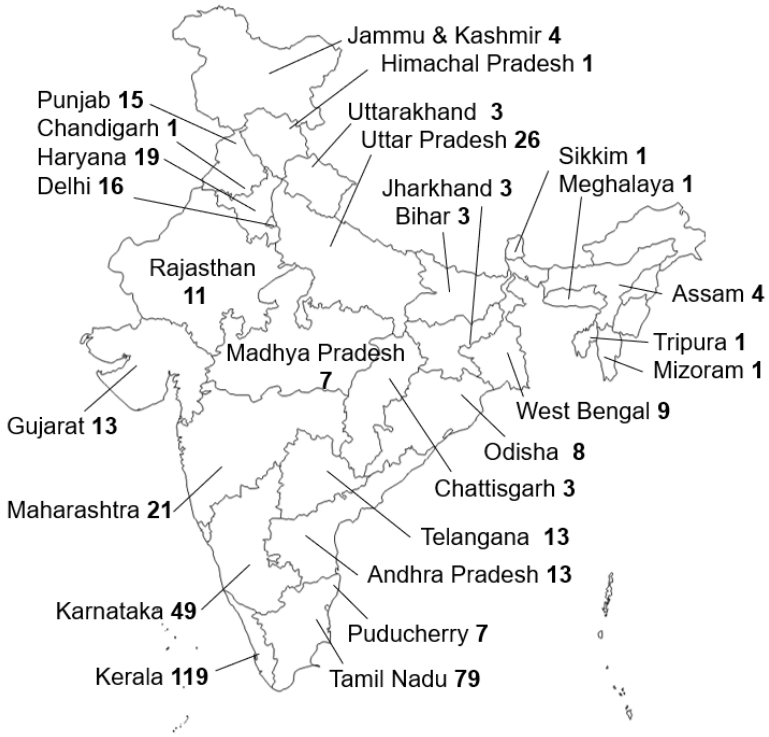


Figure 1: Medical Device Monitoring Centres under MvPI – Number of MDMCs in each State/Union Territory.

(Ref: Indian Pharmacopoeia Commission, March 2024)

Reporting of Medical Device Adverse Events in India[10]

Healthcare professionals, including clinicians, biomedical engineers, clinical engineers, hospital

technology managers, pharmacists, nurses, and other healthcare personnel, along with patients and technicians, are all encouraged to report adverse events associated with medical devices. Additionally, medical device manufacturers have the option to voluntarily submit adverse event reports specific to their products to IPC-NCC.

It is a moral responsibility of healthcare professionals and medical device manufacturers to report adverse events related to the use of medical devices. This commitment to reporting serves to safeguard public health by identifying potential risks and ensuring timely interventions.

The Materiovigilance Programme of India (MvPI) encourages the submission of adverse event reports for all types of incidents, regardless of their known or unknown nature, severity, or frequency.

Tools of Reporting

1. Using the Medical Device Adverse Event Reporting form which is available on www.ipc@gov.in, the official website of IPC.

There are two forms available. **(Figure 2.1 and 2.2).** First one is designed to be used voluntarily by manufacturers/importer/ distributer of medical devices, healthcare professionals and anyone with direct/indirect knowledge of medical device adverse event. The following details are to be filled in this form.

- General Information
- Reporter details
- Device category
- Device details
- Event description
- Patient information
- History and outcome
- Healthcare facility information
- Causality assessment
- Manufacturer/authorised representative investigation/ Action taken (applicable to manufacturer/authorized representative only)

Another simplified medical device reporting form is also available specifically for consumers/ users. This form requires only the following details to be filled.

- Patient information, history and outcome
- Suspected medical device details
- Event description/ product problem
- Reporter contact information

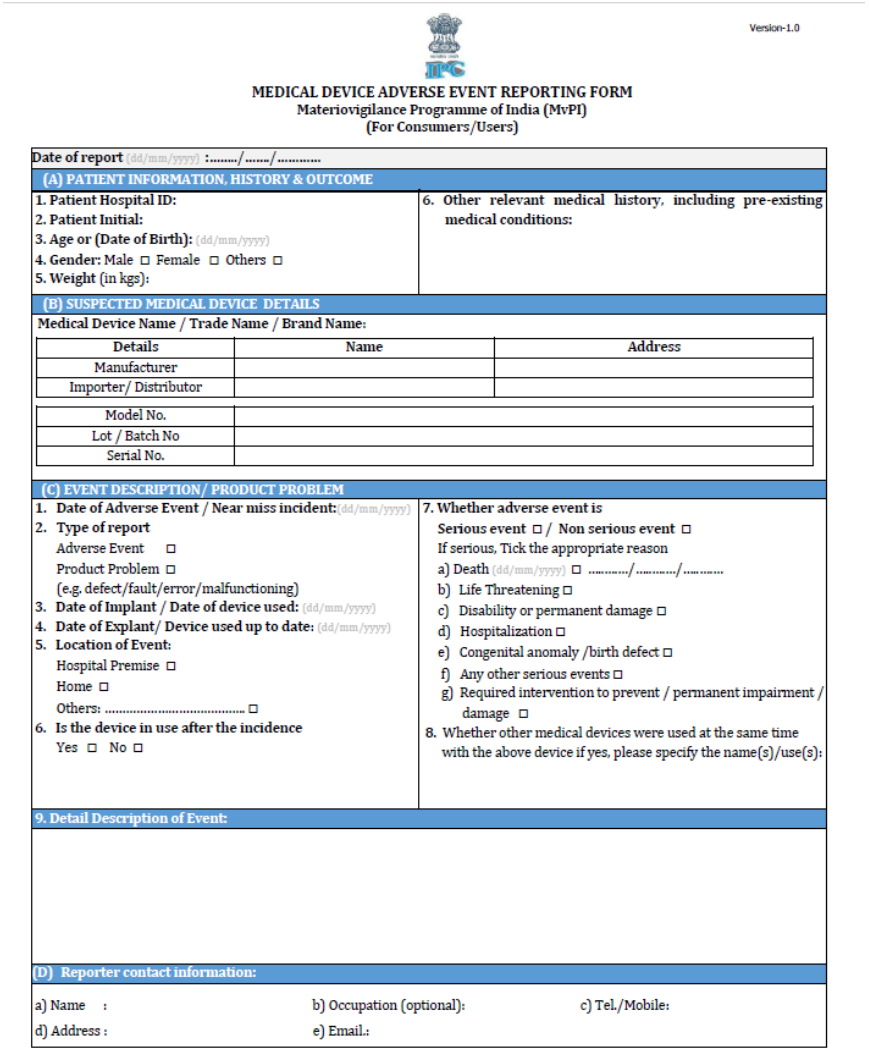
Both the forms are available in Hindi as well.

The filled form can be submitted to the nearest MDMC or directly to the National Collaborating Centre under the address IPC, Ministry of Health and Family Welfare, Government of India, Sector-23, Rajnagar, Ghaziabad-201002. Reporter can also mail the scanned form to shatrunjay.ipc@gov.in.

2. Consumers can inform the medical device related adverse events to a toll-free number 1800-180-3024, which is available between 9:00 am to 5:30 pm on Monday to Friday.

(Source: Website, Indian Pharmacopoeia Commission)

Figure 2.1: Medical device adverse event reporting form designed to be used voluntarily by Manufacturer/Importer/Distributor of Medical Devices, Healthcare Professionals and anyone with direct/indirect knowledge of Medical Devices Adverse Event.



Version-1.0

MEDICAL DEVICE ADVERSE EVENT REPORTING FORM
Materiovigilance Programme of India (MvPI)
(For Consumers/Users)

Date of report (dd/mm/yyyy) :...../...../.....

(A) PATIENT INFORMATION, HISTORY & OUTCOME

1. Patient Hospital ID:
2. Patient Initial:
3. Age or (Date of Birth): (dd/mm/yyyy)
4. Gender: Male ☐ Female ☐ Others ☐
5. Weight (in kgs):
6. Other relevant medical history, including pre-existing medical conditions:

(B) SUSPECTED MEDICAL DEVICE DETAILS

Medical Device Name / Trade Name / Brand Name:

Details	Name	Address
Manufacturer		
Importer/ Distributor		

Model No.	
Lot / Batch No	
Serial No.	

(C) EVENT DESCRIPTION/ PRODUCT PROBLEM

1. Date of Adverse Event / Near miss incident: (dd/mm/yyyy)
2. Type of report
   Adverse Event ☐
   Product Problem ☐
   (e.g. defect/fault/error/malfunctioning)
3. Date of Implant / Date of device used: (dd/mm/yyyy)
4. Date of Explant/ Device used up to date: (dd/mm/yyyy)
5. Location of Event:
   Hospital Premise ☐
   Home ☐
   Others: ..... ☐
6. Is the device in use after the incidence
   Yes ☐ No ☐
7. Whether adverse event is
   Serious event ☐ / Non serious event ☐
   If serious, Tick the appropriate reason
   a) Death (dd/mm/yyyy) ☐ ...../...../.....
   b) Life Threatening ☐
   c) Disability or permanent damage ☐
   d) Hospitalization ☐
   e) Congenital anomaly /birth defect ☐
   f) Any other serious events ☐
   g) Required intervention to prevent / permanent impairment / damage ☐
8. Whether other medical devices were used at the same time with the above device if yes, please specify the name(s)/use(s):

9. Detail Description of Event:

(D) Reporter contact information:

a) Name : b) Occupation (optional): c) Tel./Mobile:
d) Address : e) Email.:

(Source: Website, Indian Pharmacopoeia Commission)

Figure 2.2: Medical device adverse event reporting form for Consumers/Users.

Timeframe for reporting an adverse event or incident[10]

As per the Materiovigilance Programme of India (MvPI) guidance document, entities including marketing authorization holders, manufacturers, importers, and distributors are required to promptly report any suspected serious adverse events, such as fatalities, severe injuries, or device malfunctions, along with the corresponding actions taken, to both the Central Drugs Standard Control Organization (CDSCO), the National Regulatory authority, and the Indian Pharmacopoeia Commission (IPC), the National Coordination Centre, within 15 days of becoming aware of the event.

Healthcare facilities are mandated to notify suspected serious adverse events associated with medical devices to CDSCO, IPC, and the Marketing Authorization Holder within 15 days of event awareness. Non-serious events should be reported within 30 days of becoming aware of an event.

Flow of information

Healthcare professional/ market authorization holders/ con summers can report their adverse events to Medical Device Monitoring Centres or to the IPC, the National Coordination centre. From the MDMCs they are sent to NCC for central assessment. IPC facilitates collaboration among program stakeholders through the organization of steering committee and working group meetings. It also recommends suspected medical device information to CDSCO for appropriate regulatory action.

Reporting of Medical Device Adverse Events in USA – Key Points

Annually, the FDA receives a substantial volume of medical device reports of suspected device-associated deaths, severe injuries, and malfunctions. The Medical Device Reporting (MDR) system serves as a pivotal postmarket surveillance tool employed by the FDA to oversee device performance, identify potential safety concerns, and contribute to the comprehensive evaluation of product benefit-risk profiles.

Mandatory reporters, including manufacturers, device user facilities, and importers, are required to submit the FDA specific types of reports detailing adverse events and product irregularities related to medical devices. Moreover, the FDA actively encourages healthcare professionals, patients, caregivers, and consumers to voluntarily submit reports concerning serious adverse events potentially linked to medical devices, as well as instances of product misuse, quality deficiencies, and therapeutic shortcomings.[13]

The three major ways of reporting medical device related adverse events in USA are

1. Mandatory Medical Device Reporting

The Medical Device Reporting (MDR) regulation outlined in mandates specific obligations for manufacturers, importers, and device user facilities to notify the FDA of certain adverse events and product issues related to medical devices.

Manufacturers are required to inform the FDA upon learning of any instances where their devices may have directly led to or contributed to a death or serious injury. Additionally, they have to report malfunctions that could potentially result in a fatality or serious injury if the malfunction were to recur.

Importers are similarly required to notify the FDA and the manufacturer in cases where one of their imported devices is associated with a death or serious injury. If a malfunction is identified that could pose a risk of death or serious injury upon recurrence, the importer is mandated to report solely to the manufacturer.

Device user facilities, such as hospitals and outpatient treatment centres, are also subject to reporting requirements. These facilities must notify both the FDA and the manufacturer in the event of a suspected medical device-related death. Additionally, they are obliged to report incidents of medical device-related serious injuries to the manufacturer, or to the FDA if the manufacturer is unidentified.[14]

Table 1: Timeframe of Mandatory Reporting Requirements for Manufacturers, Importers and user facilities.

Reporter	What to Report	To Whom	When
Manufacturers	Deaths, serious injuries and malfunctions	FDA	Within 30 calendar days of becoming aware of an event
	Event that requires remedial action to prevent an unreasonable risk of substantial harm to the public health	FDA	Within 5 work days of becoming aware of an event
Importers	Deaths and serious injuries	FDA and the manufacturer	Within 30 calendar days of becoming aware of an event
	Malfunctions	Manufacturer	Within 30 calendar days of becoming aware of an event
User Facility	Device-related Death	FDA & Manufacturer	Within 10 work days of becoming aware
	Device-related serious injury	Manufacturer. FDA only if manufacturer unknown	Within 10 work days of becoming aware
	Annual summary of death & serious injury reports	FDA	January 1 for the preceding year

2. Voluntary Medical Device Reporting

Healthcare professionals, consumers, and patients have the option to voluntarily submit observations or suspicions of adverse events related to medical devices to the FDA. Reporting can be completed either through an online portal or by downloading, filling out, and submitting FDA Form 3500 (for healthcare professionals) or 3500B (for consumers/patients) to MedWatch: The FDA Safety Information and Adverse Event Reporting Program.

To submit a report, the individual reporting should possess at least the essential information specified below.

- Description of the adverse event or problem that occurred
- Name of the suspect device
- Reporter's name

Other details such as National Drug Code or NDC number, lot number, and expiration date should be reported when available but are not required to submit a report. The FDA assures that if requested in the form, identity of the reporter will not be disclosed to the manufacturer. Completing a report may require approximately 15 to 20 minutes.[15]

3. Voluntary Malfunction Summary Reporting Program

The Voluntary Malfunction Summary Reporting (VMSR) initiative, started in 2018, allows manufacturers

to submit select medical device malfunction reports in summary form on a quarterly basis. Under this program, manufacturers of eligible Class I and Class II devices can choose to voluntarily submit malfunction reports in a summary format quarterly, rather than utilizing the electronic format as is currently required for reporting upon becoming aware of occurrence of a malfunction.[16]

Public have access to the Manufacturer and User Facility Device Experience (MAUDE) database for details regarding medical devices that may have malfunctioned or led to a severe injury or fatality. This searchable database compiles reports of adverse events associated with medical devices. It contains the last 10 years of medical device report (MDR) data.[17]

Comparison of medical device adverse events reporting in India and USA is given in Table 2.

Table 2: Comparison of medical device adverse events reporting in India and USA.

	India	**USA**
Regulatory Authority	CDSCO	FDA
Reporting requirements	• Healthcare professionals, patients and consumers can report any adverse event related to medical devices regardless of their known or unknown nature, severity, or frequency • Marketing authorization holders, manufacturers, importers, and distributors are required to report any suspected serious adverse events, such as fatalities, severe injuries, or device malfunctions, along with the corresponding actions taken • Healthcare facilities are mandated to notify suspected serious adverse events associated with medical devices	• Unexpected side effects or adverse events can be reported by healthcare professionals, patients or consumers • Manufacturers, importers and user facilities are mandated to report medical device related death or serious injury
Timeframe for mandatory reporting	• Marketing authorization holders, manufacturers, importers, and distributors are required to report any suspected serious adverse events, such as fatalities, severe injuries, or device malfunctions, within 15 days of becoming aware of the event. • Healthcare facilities are mandated to notify suspected serious adverse events associated with medical devices within 15 days of event awareness. Non-serious events should be reported within 30 days of becoming aware of an event.	• Manufacturers should report deaths, serious injuries and malfunction within 30 calendar days and events that requires remedial action to prevent an unreasonable risk of substantial harm to the public health within 5 work days • Importers should report deaths, serious injuries and malfunctions within 30 days • User Facility should report device-related death or serious injury within 10 days
Tools of reporting	• Medical Device Adverse Event Reporting form • Toll-free number	• FDA Form 3500 (for healthcare professionals) or 3500B (for consumers/patients) – submit to MedWatch: The FDA Safety Information and Adverse Event Reporting Program • The Voluntary Malfunction Summary Reporting (VMSR) initiative - summary form • Mandatory reporting by manufacturers/ importers/ device facility
Accessibility of reports	• Periodic reports are published by the IPC	• Public can access the database MAUDE (Manufacturer and User Facility Device Experience) for medical device malfunction and adverse event details

CONCLUSION

In conclusion, the oversight and reporting of adverse events associated with medical devices are critical components of ensuring patient safety and regulatory efficacy in both India and the USA. While the regulatory frameworks and reporting mechanisms differ between

the two countries, the overarching goal remains the same: to promptly identify and address potential risks associated with medical device usage. India's materiovigilance programme and the USA's FDA serve as pivotal institutions in this regard, offering platforms for the systematic documentation and analysis of adverse events. Both countries emphasize the importance of stakeholder involvement, encouraging healthcare professionals, manufacturers, and consumers to actively participate in reporting incidents.

REFERENCES

1. Medical devices [Internet]. Who.int. [cited 2024 Apr 15]. Available from: https://www.who.int/health-topics/medical-devices
2. ICIJ, Hallman B, Starkman D, Bowers S, Schouten J, Díaz-Struck E, et al. Medical Devices Harm Patients Worldwide as Governments Fail on Safety [Internet]. ICIJ. 2018 [cited 2024 Apr 15]. Available from: https://www.icij.org/investigations/implant-files/medical-devices-harm-patients-worldwide-as-governments-fail-on-safety/
3. Center for Devices, Radiological Health. A History of Medical Device Regulation and Oversight in the US [Internet]. U.S. Food and Drug Administration. 2023 [cited 2024 Apr 15]. Available from: https://www.fda.gov/medical-devices/overview-device-regulation/history-medical-device-regulation-oversight-united-states
4. Joshi D, Sharma I, Gupta S, Singh TG, Dhiman S, Prashar A, et al. A global comparison of implementation and effectiveness of materiovigilance program: overview of regulations. Environ Sci Pollut Res Int [Internet], 2021; 28(42): 59608–29. Available from: http://dx.doi.org/10.1007/s11356-021-16345-5
5. Drugs and Cosmetics Act, 1940. [Internet]. Gov.in. [cited 2024 Apr 15]. Available from: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=OTIyNw==
6. Amravati: Four infants die as fire breaks out in incubator due to short circuit [Internet]. Latest News, Breaking News, LIVE News, Top News Headlines, Viral Video, Cricket LIVE, Sports, Entertainment, Business, Health, Lifestyle and Utility News | India.Com. 2017 [cited 2024 Apr 15]. Available from: https://www.india.com/news/india/amravati-four-infants-die-as-fire-breaks-out-in-incubator-due-to-short-circuit-2180029/
7. Raju S. Hospital incubator fire burns newborn. Hindustan Times [Internet]. 2008 Nov 17 [cited 2024 Apr 15]; Available from: https://www.hindustantimes.com/india/hospital-incubator-fire-burns-newborn/story-8rEKCWLlDmBS30N5UvHdOI.html
8. Vinayak R. 5 infants charred to death in Patiala incubator fire [Internet]. India Today. 2009 [cited 2024 Apr 15]. Available from: https://www.indiatoday.in/latest-headlines/story/5-infants-charred-to-death-in-patiala-incubator-fire-38515-2009-01-31
9. Kaunain SM. Johnson & Johnson pushed another 'faulty' hip implant in India, faces music in US, not here. The Indian Express [Internet]. 2018 Nov 30 [cited 2024 Apr 15]; Available from: https://indianexpress.com/article/express-exclusive/johnson-johnson-pushed-another-faulty-hip-implant-in-india-faces-music-in-us-not-here-5471772/
10. Guidance Document MvPI. Gov.in. [cited 2024 Apr 15]. Available from: https://www.ipc.gov.in/images/Guidance_Document_MvPI.pdf
11. Details of MDMCs under MvPI [Internet]. Gov.in. [cited 2024 Apr 15]. Available from: https://ipc.gov.in/images/451_New_MDMC.pdf
12. Medical Devices Rules, 2017. Gov.in. [cited 2024 Apr 15]. Available from: https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2022/m_device/Medical
13. Center for Devices, Radiological Health. Medical Device Reporting (MDR): How to Report Medical Device Problems [Internet]. U.S. Food and Drug Administration. 2023 [cited 2024 Apr 15]. Available from: https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems
14. Center for Devices, Radiological Health. Mandatory Reporting Requirements [Internet]. U.S. Food and Drug Administration. 2023 [cited 2024 Apr 15]. Available from: https://www.fda.gov/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities
15. Office of the Commissioner. MedWatch: FDA Safety Information & Adverse Event Reporting Program [Internet]. U.S. Food and Drug Administration. 2024 [cited 2024 Apr 15]. Available from: https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program
16. Center for Devices, Radiological Health. Voluntary Malfunction Summary Reporting Guidance [Internet]. U.S. Food and Drug Administration. 2022 [cited 2024 Apr 15]. Available from: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/voluntary-malfunction-summary-reporting-vmsr-program-manufacturers
17. Center for Devices, Radiological Health. About Manufacturer and User Facility Device Experience (MAUDE) [Internet]. U.S. Food and Drug Administration. 2024 [cited 2024 Apr 15]. Available from: https://www.fda.gov/medical-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities/about-manufacturer-and-user-facility-device-experience-maude