Journal of Advanced Zoology

ISSN: 0253-7214
Volume ***45*** *Issue* ***2*** ***Year 2024*** *Page* ***141:153***

Products Recalled During The Covid 19 Era: A Comparison Of Materiovigilance In India And Usa

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Article History

Received: 10 Dec 2023
Revised: 25 Dec 2023
Accepted: 20 Jan 2024

Abstract

The healthcare system benefits from medical devices because they are instruments that can save lives. There are a number of negative effects that these devices have in addition to their therapeutic effects. To control such unfavourable impacts, a strong cohort vigilant system was required. Material caution had been developed as a result of this. Materiovigilance entails monitoring and analysing incidents that occur as a result of the use of medical technology. It not only controls AE but also brings about international harmony.In India, the post-marketing surveillance mechanism for medical devices is less strict than it is for drugs. Materiovigilance entails monitoring unfavourable outcomes brought on by medical devices after they have been marketed. Many nations, including India, have set up their own post-marketing monitoring systems in accordance with WHO guidelines. It is referred to as the Materiovigilance Programme of India in India. (MvPI).Strict monitoring of medical devices is necessary to stop the use of those that don't reach the minimum standards for quality. If necessary, manufacturers or authorised representatives can also pull certain batches of medical devices off the market. Recall is the term used to describe any action taken by a medical device's maker or supplier to remove or withdraw the device from the market or to retrieve the device from anyone to whom it has been given because the device poses a risk to health.
A thorough understanding of adverse events related to medical devices will be provided by the comparative research of the materiovigilance programmes in India and the US. Along with existing regulations, adverse event reporting, and guidance materials, the post-market vigilance framework for medical devices was examined. In order to conduct a thorough research, data was collected from various search engines and combined.

Key words: Materiovigilance Programme of India (MvPI), Medical Device Reporting (MDR), Post-marketing surveillance, Voluntary Medical Device Reporting.

INTRODUCTION

Medical devices in India

Products that are used to diagnose, prevent, relieve, or treat a disease, disability, accident, etc. are known as medical devices. There are more than 500,000 distinct types of medical devices on the market, ranging from pacemakers and eyewear to mobile phone apps and cutting-edge surgical equipment.

Definition

Any apparatus involved in the diagnosis, mitigation, therapy, or prevention of disease and not exhibiting its effect chemically is referred to as a medical device.
Medical devices come in a wide variety of complexity and vary from two tongue depressors to highly advanced computerized medical equipment. Medical devices, as defined by the World Health Organization (WHO), are items whose principal intended mode of action is not immunologic, metabolic, or pharmacological in nature.
The Global Harmonisation Task Force (GHTF) has recommended a number of standardised terminology for medical devices. According to the WHO, medical devices may be utilised for one or more of the following stated objectives:

- Disease diagnosis, monitoring, therapy, and/or amelioration
- Identification, mitigation, monitoring, treatment, prevention, or payment for an injury
- study, replacement, or encouragement of any anatomical region or physiological process
- life's foundation and nourishment
- Controlling conception
- cleaning medical equipment

Information provided for medical purposes as a result of in vitro evaluation of specimens acquired from human body sites that fail to have the desired effect on the body through immunological, pharmacological, or metabolic activity.

Regulatory body

The Drug Controller General of India (DCGI) is in charge of the Central Drugs Standard Control Organisation (CDSCO), which is part of the ministry of health and family welfare and is responsible for managing medical device regulation. The directorate general of health services within the ministry of health & family welfare houses CDSCO, the country's national regulatory authority (NRA). Its headquarters are located at FDA Bhavan, Kotla Road, New Delhi 110002.

CDSCO

The Central Drug Authority for performing responsibilities entrusted to the Central Government under the Drugs and Cosmetics Act is the Central Drugs Standard Control Organization (CDSCO). Six zonal offices, four sub-zonal offices, 13 port offices, and seven laboratories are all under the supervision of CDSCO.[1]

Functions of CDSCO [2]

- Approval of novel drugs and clinical trials
- Registration and Licensing for Imports
- Blood banks, LVPs, vaccines, r-DNA products, and other medical devices are all subject to license approval (CLAA Scheme)
- D & C Act and Regulations Amendment
- Drug and cosmetics prohibition
- Provision of Test Licenses, Personal Licenses, and Export NOCs
- Examination of Novel Medicines
- Market surveillance and oversight through the Inspection of Center More than State Authority

Classification of medical devices based on risk in India

Class A	Low risk
Class B	Low moderate risk
Class C	Moderate high risk
Class D	High risk

Table 1: Classification of medical devices in India

Medical devices in US

A "medical device" is any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material, or other similar or related item intended for use by humans alone or in combination for one or more of the following specific medical purposes: diagnosis, prevention, monitoring, treatment, or alleviation of disease; diagnosis, monitoring, treatment, or alleviation of injury; or investment disinfection of medical equipment.[3]

Classification of medical devices in US

Device Classification	Risk	Regulatory Controls	FDA Submission/Application Type
Class I	Low to Moderate	General	510(k) Premarket Notification *Majority of devices in this class are exempt from 510(k)
Class II	Moderate to High	General and Special	510(k) Premarket Notification
Class III	High	General and Premarket Approval (PMA)	Premarket Approval (PMA)

Table 2: Classification of medical devices in US

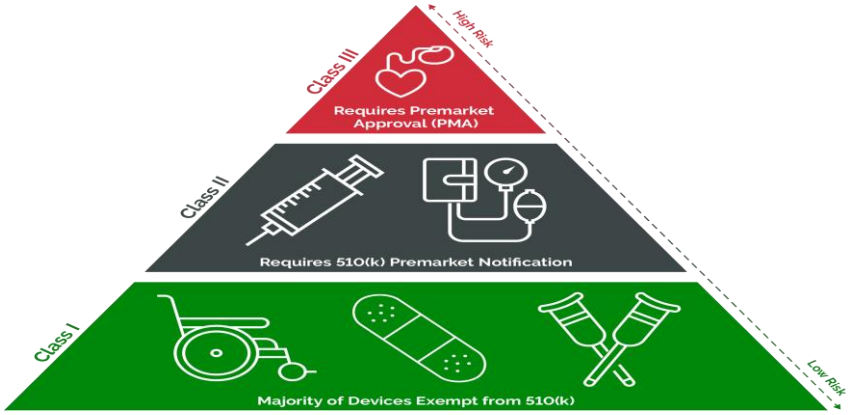


Figure 1: Classification of medical devices

METHODS AND DISCUSSION

Materiovigilance Programme of India (MvPI)

Background

On July 6, 2015, the Drugs Controller General of India (DCGI) publicly unveiled the MvPI at the Indian Pharmacopeia Commission (IPC), Ghaziabad. The Indian Pharmacopoeia Commission (IPC), an independent agency under the Ministry of Health & Family Welfare, serves as the National Coordination Center (NCC) for the country's Materiovigilance Program.

Introduction

The Materiovigilance Programme of India (MvPI) was authorised and launched by the Ministry of Health & Family Welfare, Government of India, with the specific purpose of keeping a track on the security and maintaining the calibre of medical devices utilised in the nation.

The MvPI programme attempts to encourage and make it easier to report adverse medical device occurrence and then evaluate those events. These adverse events and reports related to medical devices are evaluated scientifically and methodically, which encourages the trend-spotting necessary to improve and safeguard patients' health and safety. The Medical Device Rules 2017, which have been in place since January 2018, require that all adverse events involving medical devices be reported in order to protect patients.

The MvPI programme and its reporting mechanism are currently neglected by health facilities, and they must be actively promoted if public health issues relating to medical devices are to be addressed.

Vision

To reduce the risk associated with using medical devices by keeping track of adverse occurrences related to those devices and so improving patient safety and welfare for the Indian community.

Mission
Ensure that using medical equipment has more advantages than risks in order to protect the health of the Indian population.[4]

MDMC reporting process[5]
A committee may be established at the MDMC or the manufacturer, depending on the circumstances, and it will then discuss the preliminary findings on the event's root cause. The committee established at the MDMC may include experts such as a research associate (who prepared the initial report and is employed by the MDMC), the MDMC coordinator, biomedical and clinical engineers, hospital administration and quality officials, healthcare professionals and/or technicians handling medical devices (added on an as-needed basis based on event or incident and medical device), and others. Making the proper assessment, meanwhile, could be challenging if there are several devices and medications at play. In complicated scenarios, it should be presumed that the device connected to the event was only marginally impacted by pharmacological effects.

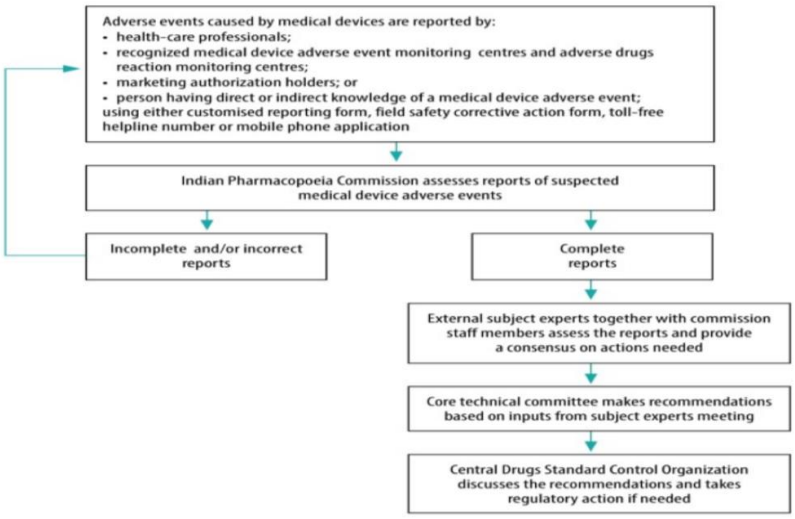


Figure 2: MDMC reporting process

Reporting requirements[4]
Who can Report
Medical device adverse events may be reported by all healthcare professionals, biomedical engineers, clinical engineers, hospital technology managers, pharmacists, nurses, HCPs (Health Care Personnel), patients, and technicians (MDAEs). Manufacturers of medical devices may voluntarily send IPC-NCC adverse occurrences that are unique to their product.

Why to Report?
It is one's moral obligation to disclose adverse events connected with the use of medical devices as a healthcare professional or ethical medical device maker, protecting the public's health in the process.

What to Report?
Although Materiovigilance is particularly concerned with adverse events connected to medical devices used in India, MvPI promotes reporting of all sorts of adverse events related to medical devices, regardless of whether they are known or unknown, serious or non-serious, frequent or rare.

How and Whom to Report?
To report any adverse events, use the Medical Device Adverse Event Reporting Form, which is accessible on the IPC's official website (www.ipc@gov.in). After completing out the aforementioned MDAE reporting form, reporters from MDMCs can submit it to the coordinator or research associate of the relevant MDMC. A reporter who is not a member of MDMC may send the completed MDAE reporting form to the National Collaborating Centre or to the MDMC that is closest to them. The scanned form can also be mailed by the reporter to mvpi.ipcindia@gmail.com with a copy to lab.ipc@gov.in. IPC has a helpline at 1800-180-3024 where people can report problems with drugs and medical equipment. To report MDAEs, a reporter can also dial this number.

Timeframe for reporting an event or Incident:

Reporter	What to report	To whom	When
Marketing authorization holder/ Manufacturers/ Importers/ Distributors	Any suspected unexpected serious adverse event incident like deaths, serious injuries, malfunction etc. and action taken thereon including any recall	National Regulatory body •National Coordination Centre – IPC	Within 15 calendar days of becoming aware of an event.
User facilities	Death, serious injuries, malfunction etc.	National Regulatory body •National Coordination Centre – IPC •Marketing authorization holder	Within 15 calendar days of becoming aware of an event. For non-serious events reporting to be done within 30 calendar days of becoming aware of an event.

Table 3: Timeframe for reporting an event or Incident

MEDICAL DEVICE ADVERSE EVENT SYSTEM[6]

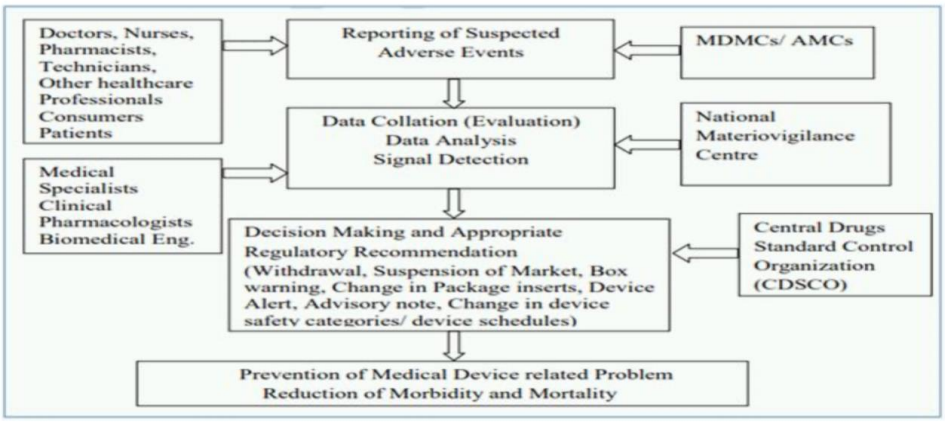


Figure 3: Medical device adverse event system in India

MATERIOVIGILANCE IN USA

Medical Device Reporting

The Food and Drug Administration (FDA) uses medical device reporting (MDR), a post-market surveillance tool, to track device performance, identify potential device-related safety problems, and contribute to benefit-risk analyses of devices. The goal of MDR is to quickly identify and respond to adverse events connected to devices. Understanding the device's post-market safety and efficacy is made possible through voluntary reporting from doctors, healthcare organisations, makers, and consumers.

MDR is applicable to all categories of medical devices, whether they are domestically produced in the USA or imported. Medical device makers must abide by MDR if they want to sell their products in the USA; failing to do so could result in financial fines. It is applicable in the USA even if a foreign event occurs, i.e., it is applicable to medical devices that are sold legally in the US and that were both made in the US and in other countries. Additionally, there are other situations in which an MDR may be applicable, including:

- When a device is produced in the USA and distributed locally as well as to other markets,
- when a device is produced in the USA but distributed in other markets,
- when a device is produced in a foreign country and supplied in the USA and other markets, and
- when a device is being investigated in the USA.[7]

Overview of Medical Device Reporting[8]

The FDA gets several hundred thousand reports of suspected device-related fatalities, severe injuries, and malfunctions each year. One of the post market monitoring strategies the FDA employs to track device performance, identify potential device-related safety problems, and contribute to benefit-risk analyses of these items is medical device reporting (MDR).

Manufacturers, device user facilities, and importers are all required to submit specific types of reports to the FDA on adverse occurrences and product issues involving medical devices. The FDA also promotes voluntary reports of major adverse events that may be connected to a medical device, as well as use errors, product quality problems, and therapeutic failures from healthcare professionals, patients, carers, and consumers. These reports, together with information from other sources, can offer vital details that enhance patient safety.
All medical device reports (MDRs) are examined by the FDA. In its consideration of MDRs, the FDA considers both the first MDR's full contents and any extra reports that could have been included later. The mere fact that an MDR was submitted is not proof that the device was to blame for the undesirable result or event. For instance, in some MDRs, the word "death" or a synonym may appear in the report's wording. However, unless the reporter feels the patient's death was caused by the device or could have been caused by it, or the device was or could have been a factor in the death, the MDR would not, and should not, be classed as a death.
MDRs are a useful source of information, however this passive surveillance technique has drawbacks. Due to underreporting of incidents, inaccurate reports, a lack of confirmation that the claimed event was caused by the device, and a lack of data regarding the frequency of device usage, the incidence, prevalence, or cause of an event cannot be determined solely from this reporting method. Due to these restrictions, MDRs only make up one of the several significant postmarket surveillance data sources used by the FDA.[9]

Mandatory Medical Device Reporting:
Manufacturers, importers, and device user facilities are required under the Medical Device Reports (MDR) regulation (21 CFR Part 803) to report to the FDA certain device-related adverse events and product defects. According to the law, reports must be submitted using the FDA's MedWatch Form 3500A or an electronic substitute. Manufacturers and importers must submit MDRs to the FDA in an electronic format so that it can process, review, and archive them, according to a final regulation that the FDA released on February 14, 2014. This regulation came into force on August 14, 2015.

Manufacturers:
When manufacturers become aware that one of their products may have led to a death or other significant harm, they are required to notify the FDA. (Key words are defined in 21 CFR 803.3.). Manufacturers are also required to notify the FDA when they learn that their product has malfunctioned and that another instance would likely result in or contribute to a death or serious harm.

Importers:
When importers discover that one of their products may have led to a death or other significant harm, they are required to notify the manufacturer and the FDA. If an imported device malfunctions and is likely to result in or contribute to a death or serious harm if it occurs again, the importer just needs to notify the manufacturer.

Summary of Mandatory Reporting Requirements for Manufacturers and Importers

Reporter	What to report	Report form	To whom	When
Manufacturers	30-day reports of deaths, serious injuries and malfunctions	Form FDA 3500A	FDA	Within 30 calendar days of becoming aware of an event
	5-day reports for an event designated by FDA or an event that requires remedial action to prevent an unreasonable risk of substantial harm to the public health	Form FDA 3500A	FDA	Within 5 work days of becoming aware of an event
Importers	Reports of deaths and serious injuries	Form FDA 3500A	FDA and the Manufacturer	Within 30 calendar days of becoming aware of an event

Table 4: Summary of Mandatory Reporting Requirements for Manufacturers and Importers

Device User Facility Reporting Requirements
A "device user facility" is a hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment centre, which is not a physician's office. A suspected medical device-related mortality must be reported to the FDA and the manufacturer by the user facility. A serious harm caused by a medical

device must be reported to the manufacturer or, in the event that the manufacturer is unknown, to the FDA by user facilities.
A user facility can voluntarily notify the FDA of such product issues through MedWatch, the FDA's Safety Information and Adverse Event Reporting Program, even though they are not compelled to do so. Healthcare practitioners should become aware with their institution's policies for informing the FDA of adverse events before working in a user facility.

Summary of Mandatory Reporting Requirements for User Facilities

Reporter	What to report	Report form	To whom	When
User Facility	Device-related Death	Form FDA 3500A	FDA & Manufacturer	Within 10 work days of becoming aware
User Facility	Device-related Serious injury	Form FDA 3500A	Manufacturer. FDA only if manufacturer unknown	Within 10 work days of becoming aware
User Facility	Annual summary of death & serious injury reports	Form FDA 3419	FDA	January 1 for the preceding year

Table 5: Summary of Mandatory Reporting Requirements for User Facilities

FDA MEDWATCH

FDA can receive voluntary reports of observed or suspected adverse events for human medical products from consumers, healthcare providers, and patients. FDA can detect unknown risk for approved medical items with the use of voluntary reporting. You can report through our online reporting portal or by downloading, filling out, and sending MedWatch: The FDA Safety Information and Adverse Event Reporting Program the FDA Form 3500 (Health Professional) or 3500B (Consumer/Patient).

Submitting Adverse Event Reports to FDA

1. Report Online
2. Consumer Reporting Form FDA 3500B. Follow the instructions on the form to either fax or mail it in for submission.
3. Call FDA at 1-800-FDA-1088 to report by telephone
4. Reporting Form FDA 3500 commonly used by health professionals.
5. MDR process flow in US

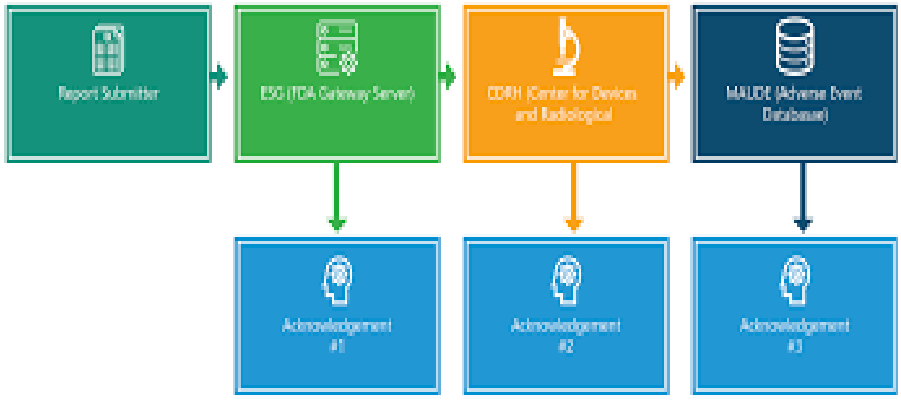


Figure 4: MDR process flow in US

eMDR – Electronic Medical Device Reporting

Manufacturers and importers must submit MDRs to the FDA in an electronic format so that it can process, review, and archive them, according to a final rule on electronic medical device reporting (eMDR) that the FDA released on February 13, 2014. Although the final regulation permits user facilities to continue submitting paper MDR reports, they can also submit eMDR reports.

Manufacturers and importers were required to start electronically reporting all MDR data by August 13, 2015. Manufacturers and importers that were unable to fulfil this deadline must apply for and be granted an exemption from electronic reporting in order to continue filing hardcopy reports beyond August 13, 2015.

Submitting to eMDR

Manufacturers and importers can submit MDRs electronically to the FDA in one of two ways:
AS2 Gateway-to-Gateway Web Interface with the eSubmitter application and HL7 ICSR XML
All electronic submissions, including eMDRs, are received through the agency-wide Electronic Submissions Gateway (ESG). In accordance with secure communications standards, the ESG serves as a single point of entry for the reception and processing of all electronic inputs.
The MedWatch 3500A electronic submission zip file must be created using eSubmitter before being uploaded to the WebTrader website by submitters using the ESG online interface.
It will be necessary for submitters who use the AS2 gateway interface to create or obtain an AS2 submission system that can produce HL7 ICSR XML and send it to the ESG.
All reporters are eligible for either choice.

Format of an electronic MDR

The FDA's current data system was created to handle, examine, and preserve MDRs that were formatted using the Health Level Seven Individual Case Safety Report (HL7 ICSR) message standard. Data element identifiers and the related data element value are included in an MDR in a machine-readable manner.

Sending an Electronic MDR Submission via FDA's Electronic Submissions Gateway (ESG)

What do I need to do to start submitting MDRs electronically to FDA?

Before receiving a production account to employ for your MDR submissions, you must first set up a Web Trader Account, submit test data, and successfully complete the ESG before you may submit MDRs electronically. The procedure to begin filing eMDRs is as follows:

1. Contact the ESG to request a Web Trader Account.
2. To the FDA, send a letter of non-repudiation.
3. Get your own digital certificate.
4. Send test results. Create a test eMDR (a fictitious report, not an actual adverse event report) with the data required by the relevant 21 CFR Part 803 section: 803.32 for user facilities, 803.42 for importers, or 803.52 for producers.
5. The ESG will send you a production account. Once you have successfully finished testing, CDRH will inform ESG to provide you the production account.
6. For your actual eMDRs to be sent to FDA, use the production account.

Preparing an electronic MDR submission

FDA eSubmitter (formerly referred to as CDRH eSubmitter or CeSub) Software

Users can create one report at a time using the eSubmitter tool, a free download. With eSubmitter, the necessary MDR data is manually entered into the eSubmitter application by the user. The application generates the.xml message in HL7 ICSR format required to effectively transmit the report via the ESG and contains data elements that are compliant with 21 CFR 803.32, 803.42, and 803.52.
The user can print a copy of the submitted report(s) and add labelling or other documents as attachments to the initial report or to a supplemental or follow-up report using the eSubmitter application.

Health Level Seven (HL7) Individual Case Safety Reporting

This option enables the creation and submission of eMDRs both individually and in groups (containing multiple individual reports in a single submission). The development of systems that can save or print the resulting report as well as encode attachments into eMDRs is urged for entities who choose this option.

How to know if the submission of an electronic MDR was successful

The user's ESG account will receive three different electronic acknowledgments automatically through the FDA's system. The acknowledgments below show what level of processing the eMDR is at:
The Reception or MDN (Message Disposition Notification) acknowledgment, also known as **Acknowledgment 1**, certifies that the ESG received the eMDR (s).
It is stated in **Acknowledgment 2** that CDRH received the eMDR (s).

The eMDR's entry into the CDRH's adverse event database is indicated in **Acknowledgement 3** with a pass or fail status, indicating if the eMDR was successfully imported into the database.[10]

RESULTS

List of products (medical devices) recalled during covid 19 in India and USA

Products recalled during covid 19 in India (2020)

Device name	Company	Reason	Date of recall	Who may be affected
rapid antigen kit	SD Biosensors	Risk of False Test Results	Dec 19, 2020	Health care providers and facilities Patients who receive breathing support

Table 6: Products recalled during covid 19 in India (2020)

Products recalled during covid 19 in India (2021)

Device name	Company	Reason	Date of recall	Who may be affected
Trilogy 100 and Trilogy 200	Philips Respironics	Silicone Sound Abatement Foam Delamination	June 2021	Health care providers and facilities Patients who receive breathing support[11]
continuous & non continuous ventilators	Philips India	polyester-based polyurethane (PEPUR) sound abatement foam used in continuous and non-continuous ventilators.	July 7, 2021	Health care providers and facilities Patients who receive breathing support[12]
Continuous Positive Airway Pressure (CPAP), and mechanical ventilator devices.	Philips	polyester-based polyurethane (PEPUR) sound abatement foam used in continuous and non-continuous ventilators.	June 14, 2021	Health care providers and facilities Patients who receive breathing support[13]
continuous ventilators	Philips India	polyester-based polyurethane (PEPUR) sound abatement foam used in continuous and non-continuous ventilators	July 8, 2021	Health care providers and facilities Patients who receive breathing support
CPAP/BiPAP ventilators	Philips India	sound abatement foam	9 august 2021	Health care providers and facilities Patients who receive breathing support

Table 7: Products recalled during covid 19 in India (2021)

Products recalled during covid 19 in India (2022)

Device name	Company	Reason	Date of recall	Who may be affected
rapid antigen kit	SD Biosensors	Risk of False Test Results	2022	Health care providers and facilities Patients who receive breathing support

Table 8: Products recalled during covid 19 in India (2022)

Products recalled during covid 19 in US (2020)[14]

Device name	Company	Reason	Date of recall	Who may be affected
Stellar 100 and 150 Non-invasive and Invasive Ventilators	ResMed	Sound Alarm Failure	02/19/20	Health care providers and facilities Patients who receive breathing support
CARESCAPE Respiratory Modules	GE Healthcare	Incorrect Oxygen Values	02/04/20	Health care providers Patients receiving treatment

Table 9: Products recalled during covid 19 in US (2020)

Products recalled during covid 19 in US (2021) [15]

Device name	Company	Reason	Date of recall	Who may be affected
SARS-CoV-2 Antigen Rapid Qualitative Test	Innova Medical Group	Risk of False Test Results	06/10/2021	People who were tested using these devices Health care providers Organizers of large testing programs
Lyra SARS-CoV-2 Assay	Quidel	Risk of False Negative Results	07/07/2021	Patients, healthcare providers, family members, and others in the community.
Ventilators and BiPAP Machines	Philips Respironics	Potential Health Risks from PE-PUR Sound Abatement Foam	07/22/2021	Health care providers Caregivers of patients
Continuous and Non-Continuous Ventilators	Philips Respironics	Risk of Exposure to Debris and Chemicals	07/22/2021	People using these devices Health care providers Durable Medical Equipment (DME) and sleep laboratories
Alinity m SARS-CoV-2 AMP Kit and Alinity m Resp-4-Plex AMP Kit	Abbott Molecular, Inc.	false positive results	10/15/2021	People who received a positive test result for SARS-CoV-2 Clinical laboratory staff and health care providers

Table 10: Products recalled during covid 19 in US (2021)

Products recalled during covid 19 in US (2022) [16]

Device name	Company	Reason	Date of recall	Who may be affected
CARESCAPE R860 Ventilator	GE Healthcare	Early Failure of Backup Batteries that May Cause Unexpected Ventilator Shut Down	06/28/2022	Health care personnel who use Carescape R860 ventilators to support patient breathing People who receive breathing support.
Certain Masks for BiPAP, CPAP Machines	Philips Respironics	Safety Issue with Magnets That May Affect Certain Medical Devices	10/18/22	People who use the recalled masks People near a person using the mask Health care personnel providing care for patients using the recalled masks
Puritan Bennett 980 Series Ventilator	Covidien, LP	Manufacturing Assembly Error	01/03/2022	Health care providers Patients
Trilogy EVO Ventilators	Philips Respironics	PE-PUR Foam	01/26/2022	People using these devices and their caregivers Health care providers
COVID-19 Tests	Empowered Diagnostics	Risk of False Results	01/28/2022	People Health care providers Distributors

Table 11: Products recalled during covid 19 in US (2022)

Products recalled during covid 19 in US (2023)[17]

Device name	Company	Reason	Date of recall	Who may be affected
Reworked Philips Respironics Trilogy 100/200 and Garbin Ventilators	Philips Respironics	Due to Potential for Silicone Foam Adhesion Failure and Residual PE-PUR Foam Debris	02/16/2023	People who receive breathing support from the affected Phillips Trilogy 100, Trilogy 200, or Garbin Plus ventilators. Health care providers and in-home caregivers
Skippack Medical Lab COVID-19 Direct Antigen Rapid Tests	Universal Meditech Inc.	Not Authorized, Cleared, or Approved by the FDA	02/08/2023	People who were tested for SARS-CoV-2 using the Skippack Medical Lab SARS-CoV-2 Antigen Rapid Test (Colloidal Gold). Health care providers and other organizations

Table 12: Products recalled during covid 19 in US (2023)

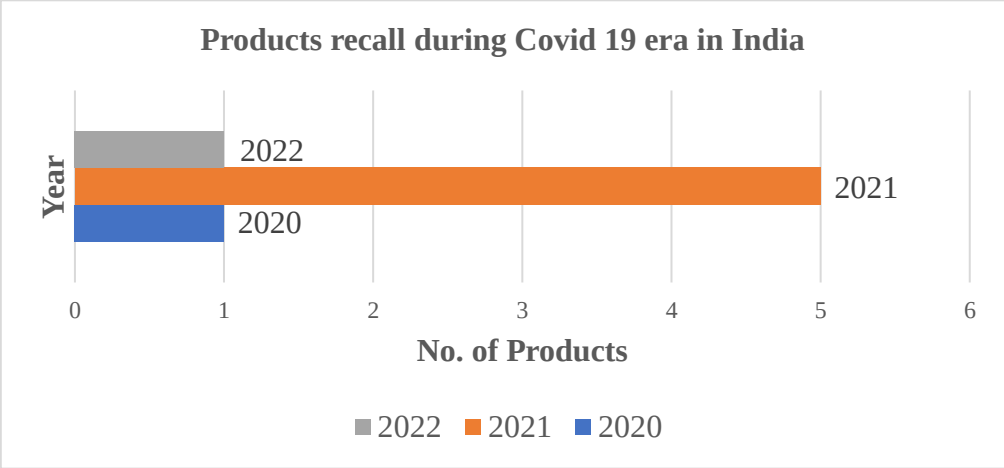
COMPARATIVE STUDY

Comparative study of materiovigilance in INDIA and USA

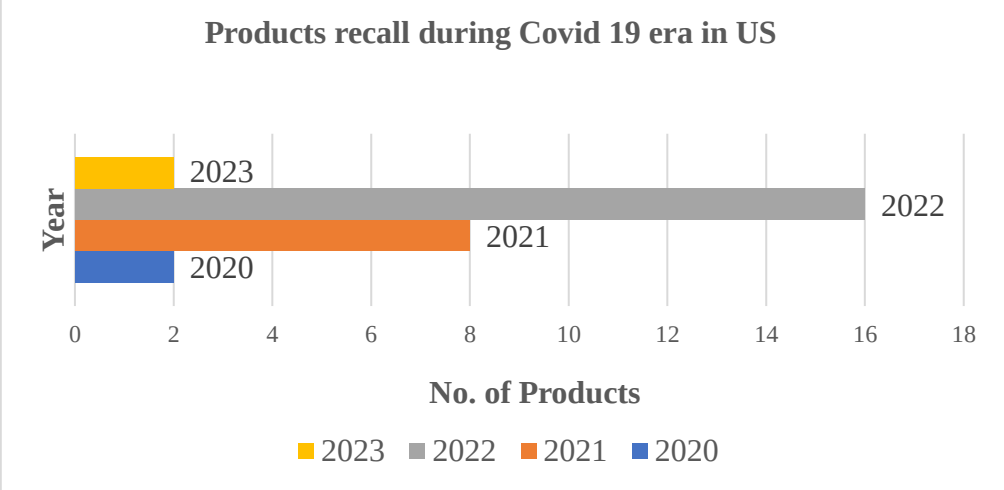
Parameters	India	USA
Definition of medical device	Any apparatus involved in the diagnosis, mitigation, therapy, or prevention of disease and not exhibiting its effect chemically is referred to as a medical device.	The term "medical device" refers to any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material, or other similar or related article intended for use by humans alone or in combination
Classification	Class A, Class B, Class C, Class D	Class I, Class II, Class III
Basis of classification	Risk based	Regulatory Controls
Post marketing surveillance	Started in 2015 under MVPI	Started in 1990 under safe medical device act
Who can report adverse events	healthcare professionals, biomedical engineers, clinical engineers, hospital technology managers, pharmacists, nurses, patients, and technicians	Manufacturers Importers Device User Facilities
Criteria for reporting	Device malfunction, serious injury, death	Death, serious injury, device malfunction
Non-reportable events	• Side effects related to medical device are expected by manufacturer's labelling. • Exceeded shelf-life of device. • Root cause of event • Deficiency found in medical device before using it.	Manufacturer can request remedial action exemption if information received is erroneous. When device is manufactured by other manufacturer.
Reporting timeline	within 15 calendar days of the event becoming apparent.	**Manufacturers** Manufacturers must submit a Medical Device Report (MDR) either within 30 days of becoming aware of an adverse event or, in the case of possible "unreasonable risk of substantial harm to the public health," within five days of learning about the event. **User device facilities** Within 10 work days of becoming aware
Types of reports	• Initial reporting • Trend reporting	• 30-day report • 5-days report

	• Final reporting	• Individual adverse event reports • Baseline report • Supplemental report • Semi-annual reports • Annual report
Recall	Manufacturers need to initiate recall	A mandatory specification for importers only
Applicable forms	• Medical device adverse event reporting form. • Field safety corrective action (FSCA) form	• FDA 3500 -Voluntary reporting of adverse events by health professionals. • FDA 3500A- Reporting a device-related death or a serious injury to the manufacturer by user facility. • FDA 3419- User facility report • FDA 3381- identifying whether the device is for prescription or OTC use.

STATISTICAL DATA



Graphical representation of Products recall during Covid 19 era in India



Graphical representation of Products recall during Covid 19 era in US

CONCLUSION

In recent years, the use of medical devices has increased. Despite this, there are not enough safeguards in place to safeguard people from unfavorable outcomes related to the use of medical devices. Materiovigilance programmes are designed to examine, track, and stop the recurrence of negative effects brought on by the use of medical devices.

In India, Silicone Sound Abatement Foam Delamination and the possibility of false results are the primary reasons why medical devices are recalled. Only a small number of products were recalled in 2020. Compared to 2020, a lot of products were recalled in 2021. Less products were recalled in 2022.
Incorrect oxygen values, the possibility of false test results, and PE-PUR Foam are the three major causes of product recalls in the US. Only 2 products were recalled in the year 2020. Eight products were recalled in 2021. 16 products were recalled in 2022. Only 2 products were recalled in 2023. The FDA website contained a listing of these devices.
Finally, I want to emphasize to companies that they should ensure that medical devices are properly designed and secure before marketing or producing them.

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