

# Comparative Study of Medical Device Vigilance in Canada, USA, Australia

Sridhar S<sup>1</sup>, Balamuralidhara V<sup>2</sup>, Balamuralidara V<sup>1</sup>

<sup>1</sup>Regulatory Affairs Group, Department. of Pharmaceutics, JSS College of Pharmacy,  
JSS Academy of Higher Education and Research, Mysuru

<sup>2</sup>Pharmaceutical Regulatory Affairs, JSS College of Pharmacy  
JSS Academy of Higher Education and Research, Mysuru

Received: 08th July, 19; Revised: 04th August, 19, Accepted: 05th September, 19; Available Online: 25th September, 2019

---

## ABSTRACT

The medical device vigilance system was set up to minimize risks to the safety of patients, users and others by detecting the possible adverse reactions in patients, the medical device safety issues are identified and reported manufacture or health professional through identification and reporting of issues by members of the public or through information sharing with other competent authorities. Medical device reporting is important from the processing and reporting of single adverse incidents through to the removal of products from the market as part of a Field Safety Corrective Action, Manufacturers are obliged to maintain robust medical device vigilance and post-marketing surveillance systems for the maintenance of the marketing authorization in the country where the product is marketed

**Keywords:** Medical device Vigilance, Reporting forms, Post-marketing surveillance

International Journal of Pharmaceutical Quality Assurance (2019); DOI: 10.25258/ijpqa.10.3.18

**How to cite this article:** Sridhar, S., Balamuralidhara, V. and Balamuralidara, V. (2019). Comparative Study of Medical Device Vigilance in Canada, USA, Australia. International Journal of Pharmaceutical Quality Assurance 10(3): 38-42.

## Objectives:

- The comparison of regulations to monitor medical device incompetent national authority, i.e. Canada, USA, Australia
- To better understand the medical device reporting requirements in the above-mentioned countries

**Source of support:** Nil

**Conflict of interest:** None

---

## INTRODUCTION

The term “medical device” includes a broad category of products ranging from therapeutic medical devices with local applications, such as tissue cutting, wound covering, or propping open clogged arteries, to highly sophisticated computerized medical equipment and diagnostic medical devices. Because these devices vary widely in type and are highly essential for patients’ care, their manufacture, distribution, and sale must be regulated to ensure their quality, safety, and efficacy

Adverse events are unintended and sometimes harmful occurrences associated with the use of the medical device. Adverse events include side effects to medical devices used. The medical device itself does not always cause an adverse event. An adverse event could be a result of incorrect user interaction or other circumstances such as two properly functioning devices that do not operate as intended when used in combination

The objective of the adverse event reporting and subsequent evaluations is to improve the protection of the health and safety of patients, users and others by disseminating information which may reduce the likelihood of, or prevent a repetition of adverse events, or alleviate consequences of such repetition.

All regulated countries have distinctly defined medical devices, but Global Harmonization Task Force (GHTF) defined a medical device as any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material, or other similar or related article, which is thereby intended to be used by the manufacturer for human beings for one or more of the specific purposes of

- Diagnosis, prevention, monitoring, treatment, or alleviation of disease or compensation for an injury
- The investigation, replacement, modification, or support of the anatomy or of a physiological process
- Supporting or sustaining life
- Control of conception
- Disinfection of medical devices
- Providing information for medical purposes by means of in vitro examination (such as reagents, calibrators, sample collection kits, control materials, and related instruments) of specimens derived from the human body and which does not achieve its primary intended action in or on the human body by pharmacological, immunological, or metabolic means, but which may be assisted in its function by such means.<sup>1</sup>

**DISCUSSION**

**Canada**

The manufacturer and the importer (subject to section 61.1 of the Regulations) are considered to be reporters of the incident to Health Canada. The complainant is the patient, user, or other person who initially brought the incident to the attention of the reporter.<sup>2</sup>

*What is a mandatory problem report?*

A mandatory problem report is required under the Regulations for any incident involving a medical device that is sold in Canada when the incident:

- Occurs either within or outside Canada;
- Relates to a failure of the device or a deterioration in its effectiveness, or any inadequacy in its labeling or its directions for use (section 59(1)(a)); and
- Has led to the death or severe deterioration of the state of health of a patient, user or other person, or could do so if it were to recur (section 59(1)(b)).
- Note: This guidance document interprets “sold” to mean “authorized for sale” (for Class II, III, IV medical devices), regardless of whether any units have yet been distributed.

The manufacturer and importer are required to make both a preliminary and a final mandatory reports unless the manufacturer provides the minister written authorization to permit the importer to report on its behalf (see section 61.1(1)-61.1(2) of the Regulations). Manufacturers remain responsible for ensuring that the information in the incident report is both complete and accurate.

A mandatory problem report is required under section 59(2) of the regulations for any incident occurring outside Canada (foreign incidents), but involving a medical device that is also sold in Canada, only if the manufacturer has informed the regulatory agency in the country where the incident occurred that corrective action is necessary, or when this regulatory agency has requested the manufacturer to take corrective action.<sup>3</sup>

*Criteria to determine reportability?*

An incident has occurred

The reporter becomes aware of information regarding an incident which has occurred with its device. This may include information from device testing performed by the manufacturer, user or another party

*The device contributed to the incident*

- In assessing the link between the device and an incident, the reporter should take into account:
- the opinion, based on available information, from a health professional;
- information concerning previous, similar incidents;
- complaint trends; and
- Any other information held by the reporter.

*The incident lead to one of the following outcomes*

- Death of a patient, user or another person
- Serious deterioration in the health of a patient, user or another person
- Potential for death or serious deterioration in health of a patient, user or another person.

**United States**

Medical Device Reporting (MDR) is one of the postmarket surveillance tools the FDA uses to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments of these products.

Mandatory reporters (i.e., manufacturers, device user facilities, and importers) are required to submit certain types of reports for adverse events and product problems to the FDA about medical devices. In addition, the FDA also encourages health care professionals, patients, caregivers, and consumers to submit voluntary reports about serious adverse events that may be associated with a medical device, as well as use errors, product quality issues, and therapeutic failures. These reports, along with data from other sources, can provide critical information that helps improve patient safety.<sup>5</sup>

**Mandatory Medical Device Reporting Requirements:**

The medical device reporting (MDR) regulation (21 CFR 803) contains mandatory requirements for manufacturers, importers, and device user facilities to report certain device-related adverse events and product problems to the FDA.

*Manufacturers*

Manufacturers are required to report to the FDA when they learn that any of their devices may have caused or contributed to a death or serious injury. Manufacturers must also report to the FDA when they become aware that their device has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

**Mandatory Problem Reporting for Medical Devices: <sup>5</sup>**

<i>Reporter</i>	<i>Report what</i>	<i>To whom</i>	<i>When</i>
Consumers and health professionals	Unexpected, regardless of their severity, Serious, whether expected or not, Reactions to recently marketed health products	Health Canada	The date at which the incident with the medical device occurred
Industry	Unexpected, serious or problem in the device usage	Health Canada	The date at which the incident with the medical device occurred

**Importers**

Importers are required to report to the FDA and the manufacturer when they learn that one of their devices may have caused or contributed to a death or serious injury. The importer must report only to the manufacturer if their imported devices have malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

**Device User Facilities**

A device user facility is a hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment facility, which is not a physician’s office. User facilities must report a suspected medical device-related death to both the FDA and the manufacturer. User facilities must report a medical device-related serious injury to the manufacturer, or to the FDA if the medical device manufacturer is unknown.

A user facility is not required to report a device malfunction but can voluntarily advise the FDA of such product problems using the voluntary MedWatch Form FDA 3500 under FDA’s Safety Information and Adverse Event Reporting Program. Healthcare professionals within a user facility should familiarize themselves with their institution’s procedures for reporting adverse events to the FDA. See «Medical Device Reporting for user facilities», a guidance document issued by FDA.<sup>6</sup>

**Australia**

Adverse events are unintended and sometimes harmful occurrences associated with the use of a medicine, vaccine

or medical device (collectively known as therapeutic goods). Adverse events include side effects to medicines and vaccines, and problems or incidents involving medical devices.<sup>8</sup>

In the case of medical devices, an adverse event can also be a problem or incident that has caused or could cause, harm to patients, caregivers, health professionals, or others. These can include ‘near misses’ – events that might have led to a death or serious injury. It may be that timely intervention from a health professional prevented an adverse event.

Importantly, an adverse event is not always caused by the therapeutic good itself. An adverse event could be a result of incorrect user interaction or other circumstances such as two properly functioning devices that do not operate as intended when used in combination. The occurrence of an adverse event does not necessarily mean that there is something wrong with the therapeutic good.<sup>9</sup>

**EARLY WARNING SYSTEM**

The early warning system includes current and historical information on safety concerns for medical devices (also known as therapeutic products) that the TGA has identified through its therapeutic product vigilance program.<sup>10</sup>

There are two types of communications that can be issued as part of the Early Warning System:

**Monitoring Communications**

These early communications are intended to highlight potential safety concerns that are identified by the TGA. In addition, the TGA aims to encourage further reporting and research to provide more information on these safety concerns. These concerns have not been fully investigated.

**MDR Reporting Requirements<sup>7</sup>**

<i>Reporter</i>	<i>Report what</i>	<i>To whom</i>	<i>When</i>
User Facility	Deaths	FDA Manufacturer	Within 10-working days
	Serious injuries	Manufacturer FDA only if manufacturer unknown	Within 10-working days
	Semi-annual report of deaths and serious injuries	FDA	January 1 and July 1
Manufacturer	30-day reports of deaths, Serious F and malfunctions	FDA	30- days from becoming aware
	Baseline report to identify and provide basic data on each device that is subject of a report	FDA	With 30-day report when a device is reported for the first time
	5 days report on events that require immediate remedial action and other types of events designated by FDA	FDA	Within five working days
	Annual certification of compliance with regulation	FDA	When a firm submits an annual registrations
Exemptions, Variances, and Alternative Reporting	Investigational devices are exempt, exemptions, variances or alternatives to any or all of the reporting requirements may be granted upon request or at the discretion of FDA		

**MDR Reporting Requirements<sup>12</sup>**

<i>Reporter</i>	<i>Report what</i>	<i>To whom</i>	<i>When</i>
Consumers	serious adverse events like death, danger to life, admission to hospital	TGA Manufacturers	serious deterioration – 10 calendar days Reportable near adverse event – 30 calendar days
Health Professionals	serious adverse events like death, danger to life, admission to hospital	TGA Manufacturers	Serious public health threat requiring remedial action – 48 h
Industry	Serious adverse event Suspicious adverse event	TGA TGA	serious deterioration – 10 calendar days Reportable near adverse event – 30 calendar days

**Comparison of vigilance reporting<sup>13, 14, 15</sup>**

<i>Parameter</i>	<i>Canada</i>	<i>US</i>	<i>Australia</i>
Definition of medical device	Covers a wide range of health or medical instruments used in the treatment, mitigation, diagnosis or prevention of a disease or abnormal physical condition.	Includes all instruments, appliances, materials, machines, in vitro diagnostic agents, implants, software, accessories, and disinfectants	Excludes tampons and hospital, household, and commercial-grade disinfectants
Regulatory authority	Health Canada	US Food & Drug Administration	Therapeutic Drug Administration
Medical device classification	4 classes: Class I, II, III and IV	3 classes: class I, class II, and class III	5 classes: class I, classes II a and II b, class III, and class AIMD
Criteria for reporting	Death of a patient Serious, deterioration in health of a patient, user or other person Potential for death or serious deterioration in health of a patient, user or other person	Death or serious injury Device malfunctions User error Injury/illness requiring medical intervention	Event has occurred Medical device's association with the event Event led/might lead to death/serious injury
Product	Medical Device	Medical Device	Medical Device or Therapeutic Product
Regulation	Medical Devices Regulations SOR-98-282	21 CFR 803	ARGMD Part 3, Section 22
Reporting type	Online	Online	Online
Reporting forms	Medical Device Problem Reporting Form	Health professionals- FDA form 3500 Customer/Patient- FDA form 3500B Manufacturer/Importer /Distributor- FDA form 3500A	Medical Device Incident Report
Link for forms	<a href="https://apps.tga.gov.au/prod/mdir/udir03.aspx?sid=1741132331">https://apps.tga.gov.au/prod/mdir/udir03.aspx?sid=1741132331</a>	<a href="https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home">https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home</a>	<a href="https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html">https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html</a>

**Alert Communications<sup>11</sup>**

These communications are issued once a safety concern has been investigated. Alerts contain more information on the safety concern and provide advice on actions that may need to be taken by health professionals and consumers.

**CONCLUSION**

The medical device should be mandatorily reported to the competent authority to safe guard the health of the patients by the manufacturer or sponsor, the each country have its own type of requirements for the reporting of the medical device adverse event should be understood by the health professionals and manufacturer and it is reported mandatorily for safe guard the public health

**REFERENCE:**

1. Gupta P, Janodia MD, Jagadish PC, Udupa N. Medical device vigilance systems: India, US, UK, and Australia. *Med Devices (Auckl)*. 2010 Nov 22;3:67–79.
2. Canada H, Canada H. Medical Devices [Internet]. *aem*. 2004 [cited 2018 Aug 21]. Available from: <https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices.html>
3. Canada H, Canada H. Adverse Reaction and Medical Device Problem Reporting [Internet]. *aem*. 2002 [cited 2018 Aug 21]. Available from: <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>
4. Canada Vigilance Program, Canada, Health Canada, MedEffect Canada. Guidance document for mandatory problem reporting for medical devices. [Internet]. Ottawa: Health Canada; 2011 [cited 2018 Jul 3]. Available from: [http://publications.gc.ca/collections/collection\\_2012/sc-hc/H164-145-2011-eng.pdf](http://publications.gc.ca/collections/collection_2012/sc-hc/H164-145-2011-eng.pdf)
5. Commissioner O of the. Reporting Serious Problems to FDA - What is a Serious Adverse Event? [Internet]. [cited 2018 Aug 21]. Available from: <https://www.fda.gov/Safety/MedWatch/HowToReport/ucm053087.htm>
6. <https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>
7. Canada H, Canada H. Adverse Reaction Database [Internet]. *aem*. 2009 [cited 2018 Aug 21]. Available from: <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-database.html>
8. Medical Device Incident Reports [Internet]. [cited 2018 Aug 21]. Available from: <https://apps.tga.gov.au/prod/mdir/udir03.aspx?sid=1435837464>
9. Sg G. Adverse Event Reporting Guidance for the Medical Device Manufacturer or its Authorized Representative. 1999;11.
10. Administration AGD of HTG. Reporting adverse events [Internet]. Therapeutic Goods Administration (TGA). 2018 [cited 2018 Aug 21]. Available from: <https://www.tga.gov.au/reporting-adverse-events>
11. Administration AGD of HTG. Early warning system [Internet]. Therapeutic Goods Administration (TGA). [cited 2018 Aug 21]. Available from: <https://www.tga.gov.au/early-warning-system>
12. Administration AGD of HTG. Medical devices regulation basics [Internet]. Therapeutic Goods Administration (TGA). [cited 2018 Aug 21]. Available from: <https://www.tga.gov.au/medical-devices-regulation-basics>
13. Health. Therapeutic Goods (Medical Devices) Regulations 2002 [Internet]. [cited 2018 Aug 21]. Available from: <https://www.legislation.gov.au/Details/F2018C00490/Html/Text>, <http://www.legislation.gov.au/Details/F2018C00490>
14. Canada Vigilance Program, Canada, Health Canada, MedEffect Canada. Guidance document for mandatory problem reporting for medical devices. [Internet]. Ottawa: Health Canada; 2011 [cited 2018 Aug 21]. Available from: [http://publications.gc.ca/collections/collection\\_2012/sc-hc/H164-145-2011-eng.pdf](http://publications.gc.ca/collections/collection_2012/sc-hc/H164-145-2011-eng.pdf)
15. <https://www.emergobyul.com/sites/default/files/usa-fda-medical-device-reporting-21-cfr-part-803.pdf>