Do you know the requirements and your responsibilities for medical device vigilance reporting?

A detailed review on the requirements of MDSAP participating countries in comparison with the European Medical Device Regulation 2017/745

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Introduction

Medical devices are regulated differently across the globe. Each country/region has mandated the requirements around what medical devices are, their classification rules, the obligations that need to be met to place medical devices on the market and the post-market requirements once commercialization has taken place.

Many articles have been published on the need to balance safety and performance with timely access to innovation. Some of these publications go on to compare the strengths and weaknesses of various global regulatory systems. All medical devices carry some level of risk and may, when in clinical use, suffer mechanical, electrical or biological failures, be damaged, be used incorrectly or experience such an issue which may result in death or serious deterioration in the health of patients. When these events occur they must be reported to the appropriate regulatory agency in the region where they occurred. It is also a requirement for some of this information to be shared in other regions where the same device is placed on the market.

The International Medical Device Regulators Forum[1] (IMDRF) is an organization comprised of medical device regulators from Australia, Brazil, Canada, China, the EU, Japan and the USA with the desire to accelerate global medical device regulatory harmonization and convergence. One of their recent initiatives is to allow conformity assessment for several regions to be conducted in one audit, known as the Medical Device Single Audit Program (MDSAP). This paper outlines the requirements specific to incident reporting, vigilance, mandatory problem reporting, medical device reports and adverse event reporting, herein termed 'vigilance', in comparison with the requirements of the recently published European Medical Device Regulation (MDR) to support those working with these aspects within the MDSAP Program. Manufacturers who wish to supply their devices outside of these regions may have many more requirements to meet, the discussion of which is beyond the scope of this paper.

1 http://www.imdrf.org/

What are the requirements?

Table 1 – Summary of vigilance requirements across MDSAP participating countries and the MDR (Europe). Further details can be found in Appendix 1.

Country	Australia	Brazil	Canada	Japan	USA	Europe (MDR)
Regulatory Agency/ Authority	Therapeutic Goods Association (TGA)	Agência Nacional de Vigilância Sanitária (ANVISA)	Health Canada	Ministry of Health, Labour and Welfare/ Pharmaceuticals and Medical Devices Agency	The Food and Drug Administration (FDA)	The Competent Authority of the Member State in which that incident occurred
Who reports	– Manufacturers – Australian Sponsor	– Manufacturers – Brazilian Registration Holder	– Manufacturers – Canadian Importer	– Market Authorization Holder	– Manufacturers – Importers	– Manufacturers
What to report and when	'Serious Threat to Public Health' no later than 2 days after becoming aware	'Death', 'Serious Public Health Threats' and 'Counterfeit Devices' no later than 3 days (72 hours) after becoming aware	Serious deterioration in health also includes a serious public health threat which is any incident type, which results in imminent risk of death, serious deterioration in health, or serious illness that requires prompt remedial action – see below	Market Authorization Holder should report the matters specified in the items of Article 228-20, Paragraph 2 of the Enforcement Regulations concerning the products when the institutions and relevant registered manufacturing sites have cognizance of the matters concerned	Form FDA 3500A should be submitted within 5 days of becoming aware of an event that requires remedial action to prevent an unreasonable risk of substantial harm to the public health	'Serious Public Health Threats' no later than 2 days of becoming aware
	'Adverse Events' no later than 10 days after becoming aware	'Major Adverse Events' and 'Minor Adverse Events, whose recurrence has the potential to cause a major adverse event' no later than 10 days after becoming aware	A mandatory problem report should be submitted within 10 days of becoming aware when a patient, user or other person died or experienced a serious deterioration of health as a result of the event	Translation from Ministry of Health, Labour and Welfare (MHLW) Ordinance No. 135 of 2004 – Good Vigilance Practice: Death Impediment Cases with the possibility of death or impediment Hospital admission to alleviate impediment or cases that extend hospital admission Congenital diseases (Within 15 calendar days)		'Serious Incidents' no later than 10 days of becoming aware
	'Near Adverse Event' no later than 30 days after becoming aware	'Technical Complaints, which may lead to a major adverse event, if at least one of the following conditions are met: *– possibility of technical complaint recurrence is not remote;* *– a similar occurrence has already caused or contributed to death or major health damage [adverse event] in the last 2 years;* *– the manufacturer would need to carry out action to prevent a serious public health threat;* *– it is likely the error of use.'* *– No later than 30 days after becoming aware*	A mandatory problem report should be submitted within 30 days of coming aware when the event could have caused or contributed to a serious deterioration of health or death	The same cases as described above that could be attributed to the malfunction of the medical device within 30 calendar days	Form FDA 3500A should be submitted within 30 day of becoming aware of reports of deaths, serious injuries and malfunctions	'Incidents' no later than 15 days of becoming aware

(*Continued*)

Table 1 – (*Continued*)

Country	Australia	Brazil	Canada	Japan	USA	Europe (MDR)
Reporting required for events outside country	No	If the event is associated with a registered medical device outside of Brazil and the model/batch or serial number was imported into Brazil, the reporting criteria include 'Death', 'Serious Public Health Threats' and 'Counterfeit Devices' no later than 10 days after becoming aware	No *Note:* There is one exception to this that is outlined in Section 59(2) in the regulation: a foreign incident which resulted in the decision to undertake a field action should be reported to Health Canada provided it also meets the reporting requirements set forth in Section 59(1) of the regulations	Yes – adverse events that occur worldwide that are associated with products approved for sale in Japan should be reported to Pharmaceuticals and Medical Devices Agency (PMDA)If the device involved in an adverse event is manufactured using similar manufacturing processes, even if it is not sold in Japan and depending on the issue, it is subject to reportability	Yes – US manufacturers of medical devices that are not cleared or approved in the USA, but are exported to foreign locations, are also subject to the Medical Device Reporting regulation	Yes – any field safety corrective action in respect of devices made available on the Union market, including any field safety corrective action undertaken in a third country in relation to a device which is also legally made available on the Union market, if the reason for the field safety corrective action is not limited to the device made available in the third country
Can patient data be requested (e.g. age, weight, gender)	No	Yes	No	Yes	Yes	No
Trend or Periodic Reporting required	Annual reports are submitted for the first 3 years the device is approved for market	No	No	No	Although not a Trend or Periodic Report, Alternative Summary Reporting (ASR) is in place for a large number of similar reports which reduces the volume of supplemental reports. Approval from the FDA is required before submission	Yes – Trend Reporting (Article 88) and Periodic Summary Reporting (Article 87)
How to report	Via IRIS	Via SNVS	Via email, fax (613-954-0941) or mail: Canada Vigilance – Medical Device Problem Reporting Program Marketed Health Products Directorate Health Canada Address Locator 1908C 200 Eglantine Driveway Ottawa, Ontario K1A 0K9	To consult by telephone with PMDA and upload to the designated website page of PMDA	The FDA has two options for manufacturers and importers to electronically submit Medical Device Reports: Web Interface using the eSubmitter application AS2 Gateway-to-Gateway using HL7 ICSR XML	Via EUDAMED*

*At the time of publication of this White Paper, the EUDAMED Database is under construction and is planned to go live in 2019.

Considerations

To support compliance to the vigilance requirements listed in Table 1, it is important to consider the aspects of a quality system (such as ISO 13485:2016) which allow for the collection of the appropriate information which will support compliance to those requirements. ISO 13485:2016 now includes a clause (8.2.3) on reporting applicable complaints to the affected regulatory authorities, which further emphasizes the need for manufacturers to have documented procedures to allow for these to be made. If these processes are not clearly established, compliance to those regulatory requirements will not be possible.

Complaint Handling Procedure

To support the reporting of vigilance, a Complaint Handling Procedure should be established to facilitate the process. This may include:

- The definition of a complaint, which needs to be broad enough to ensure compliance to vigilance requirements in all regions a device is placed on the market.
- Confirmation on how the awareness date of the complaint is confirmed to allow a deadline for vigilance reporting to be established.
- A mandate for company employees to report complaints within a set period to allow vigilance reporting to be completed in due time, noting that complaints which involve a patient death need to be reported to some Regulatory Authorities as soon as three working days after becoming aware (Brazil).
- A Complaint Form, which includes methods of capturing all of the information needed to complete the necessary vigilance reporting forms wherever the device is being marketed, including any patient specific data wherever data privacy rules allow collection of such data. Other aspects to consider within a Complaint Form include:
  - Employee complaint awareness date
  - Device catalogue number
  - Device batch/lot number
  - Date of procedure/use
  - Event description, including when and how the issue was noted, and the patient outcome
  - Implant/explant date (where applicable)
  - Confirmation on whether the device will be returned for further investigation
- Other methods to report complaints can be established, including local telephone numbers, email addresses and other appropriate contact details to competent staff who can collate the required information.
- A process for obtaining the complaint product(s) back, or images from a procedure to allow for a thorough investigation to be completed and a root cause established wherever possible.
- The process for how an investigation into a product complaint will be performed, within a defined period to allow the final/follow-up conclusion to be submitted to the regulatory agency within due time.
- A trending process which allows the escalation of any product issues so that further action can be considered where required (e.g. a recall, Field Safety Corrective Action).

Vigilance Procedure

To support the assessment of complaints for vigilance reportability, a Vigilance Reporting Procedure should be established. Such a procedure could incorporate tools such as a vigilance reporting decision making tree to allow for region-based reporting decisions to be made in one step. Other considerations include having separate vigilance reporting procedures for individual regions, so that one region's more stringent requirements can be counter-balanced with other regions less stringent requirements from a workload and deadline perspective. Consideration should be made as to how this should be documented, noting that definitions for event terms can vary from region to region. This procedure should be regularly reviewed to ensure it accurately reflects the most current regulatory requirements, and may include:

- The applicable vigilance regulations of the geographies the procedure covers, including definitions of event terms
- How to determine whether the complaint is reportable with the information made available, and in which geography it would need to be reported. Table 1 may be helpful in this assessment

- Use of the device's Risk Management documentation in helping to understand in advance those events which would be considered reportable may facilitate consistent and prompt compliance to reporting deadlines
- How and where to document the reporting rationale, considering the caveat that if ever there is an uncertainty on whether a complaint is reportable that there should be a pre-disposition to report
- Instruction on how to complete the report, including any standard wording used to describe specific incidents
- Procedure for having medical input should the event involve patient conditions, for example having a physician review a video of the procedure to assist in determining how the device performed, should this be made available to the manufacturer
- Having the appropriate regulatory information about each marketed product easily accessible (such as classification, regulatory agency registration number) so that this does not delay the completion of the report
- Confirmation on who is responsible for translation of the report into the local language where applicable
- The process of obtaining additional information from the user to assist with the completion of the report and how this should be documented, again noting the caveat that a report should not be delayed should information be missing
- Instruction on who should submit the report, how they should submit it, how to record that the report has been delivered and subsequent regulatory agency receipt
- Who is responsible and the process to be followed for any requests or additional information from the regulatory agency
- Having any previous field action documentation easily to hand, so that should a root cause of a device failure be confirmed to be related to a historical field action that this information can be documented in the vigilance reporting form
- The process followed for complying with any Trend/Periodic Summary Reporting requirements

Training

Complaint Handling and Vigilance Reporting processes will only be successful when all employees, and relevant other parties (such as distributors and professional end-users) are appropriately trained. Should the device be sold directly to the end user (patient), manufacturers may want to consider including easy to follow guidance in the packaging and/or Instructions for Use (IFU) for complaint reporting. All training should be appropriately documented.

Audit

When conducting internal audits, audits of suppliers or subcontractors where such activities are delegated and those that conduct third party conformity assessment audits it is important to ensure that there is a system in place that allows for compliance to the regulations and that this is effective.

The importance of an effective vigilance system

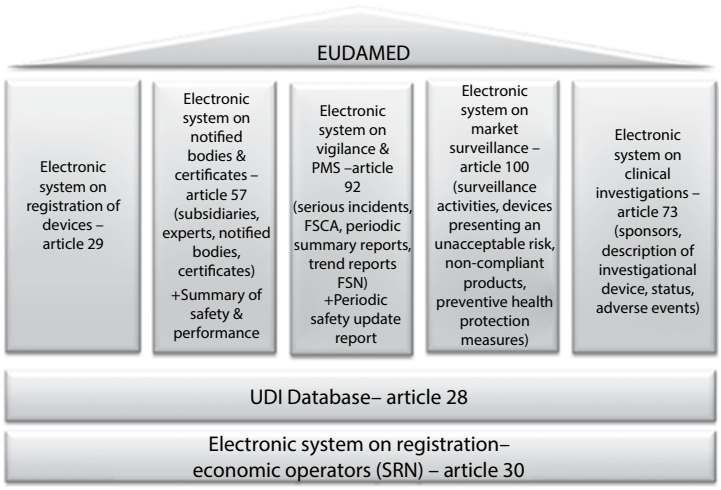
The value in having a sound vigilance system in place cannot be underestimated. Meeting vigilance reporting regulatory requirements should be considered as one output of having an effective Quality System in place. Complaint and vigilance data can feed into a Post-Market Surveillance programme supporting the device's Technical Documentation, such as the Clinical Evaluation and Risk Management, allowing for a continued assessment to be made that a device is safe and performing as anticipated. In addition, it can also assist in flagging performance issues with a device so that an assessment can be made whether the device needs to be re-designed, recalled, withdrawn or can help in confirming whether alternative/updated instructions for users are required to achieve the intended performance and the safe use of the device. Data from an effective vigilance system can feed into any Periodic Summary Reporting arrangements made with Regulatory Agencies, and finally, into Research and Development (R&D), allowing for considerations to be made when designing the next generation of device.

Transparency

With the digital age that we currently live in, patients and users are often turning to the information available online to make assessments on what device they would like to use or be treated with. With this, and the continued scrutiny on whether regulatory systems around the world are adequate, transparency on the safety and performance of medical devices is becoming increasingly important.

The information made available to the public in each of the five countries versus the European Union is interesting to compare:

- Australia's Database of Adverse Event Notifications (DAEN) has been publicly available since 2012 and is searchable by report number, date, manufacturer, sponsor, device name, device Global Medical Device Nomenclature (GMDN) or Australian Registry of Therapeutic Goods (ATRG) number. Incidents are assigned an event type code from ISO/TS 19218-1:2011 – Medical devices – Hierarchical coding structure for adverse events – Part 1: Event-type codes.
- US FDA's Medical Device Reporting database was superseded by the Manufacturer and User Facility Device Experience (MAUDE) database which has been publically available since 1996. MAUDE is searchable by report number, date, manufacturer, device name, device class, event type or product problem. The Product Problems are divided into more than 1000 device problems and patient problems described by 3500A Code Manual.
- Japan and Brazil have publically available information on incidents available only in their local languages.
- The new MDR takes a step forward in improving access to vigilance information and market surveillance as a whole in Europe. The MDR wording includes reference to the European database on medical devices EUDAMED (Article 33). EUDAMED will aid transparency, as information will be made available, with varying access levels, to competent authorities, economic operators, notified bodies, sponsors, healthcare professionals and patients subsequently contributing to increased patient safety.



One of the objectives of EUDAMED is to enhance transparency by allowing information for the public and healthcare professionals to be easily available

Further efforts by individual countries, combined efforts of the EU Member States and the IMDRF will have to be completed to harmonize numeric codes to describe device problems, cause investigation terms/codes, patient problem terms/codes and component terms/codes. When these are complete the international exchange of information (IMDRF Medical Devices: Post-Market Surveillance: National Competent Authority Report) will be able to realize trends in global safety data and aid in early detection of signals related to safety and performance issues.

MDSAP participating countries

Conclusion

Manufacturers need to be aware and understand vigilance reporting requirements of all of the jurisdictions that they operate under. Robust, well-documented complaint and vigilance reporting processes/procedures need to be in place not only to meet the regulatory requirements, but also to provide evidence to manufacturers that their medical device continues to operate as designed, is performing as anticipated, and remains state-of-the-art. Depending on countries in which manufacturers place devices on the market will determine the most stringent requirements to follow.

Manufacturers should also consider that at the time of publication of this White Paper, the EUDAMED Database to support compliance to the MDR is under construction and is planned to go live in 2019. Manufacturers will still have an obligation to report under the MDR should the EUDAMED database not go live before the date of application in May 2020. This also applies to manufacturers placing devices on the market with a valid CE Certificate issued under the current Directives, and issued before the end of the 3-year transition period. All devices must meet the MDR requirements by May 2024.

Continued efforts on improving market surveillance across the world including those being made by the IMDRF are expected to have a significant impact globally on improving patient/user safety in the future.

Appendix 1 – Vigilance requirements across MDSAP participating countries and the MDR (Europe)

European Union and the European Economic Area (EEA) – Member States (http://ec.europa.eu/growth/sectors/medical-devices/)

The Medical Devices Regulation (MDR) was published on 5 May 2017 and entered into force on 26 May 2017.

Who reports	Manufacturers
What to report	(a) any serious incident involving devices made available on the Union market, except expected side-effects which are clearly documented in the product information and quantified in the technical documentation and are subject to trend reporting pursuant to Article 88 (Article 87 (a) & (b)) (b) any field safety corrective action (FSCA) in respect of devices made available on the Union market, including any FSCA undertaken in a third country in relation to a device which is also legally made available on the Union market, if the reason for the field safety corrective action is not limited to the device made available in the third country Definitions: 'Incident' means any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side-effect (Article 2 (64)) 'Serious Incident' means any incident that directly or indirectly led, might have led or might lead to any of the following: (a) death of a patient, user or other person, (b) the temporary or permanent serious deterioration of the patient's, user's or other person's state of health, (c) serious public health threat (Article 2 (65)). 'Serious Public Health Threat' means any event which could result in imminent risk of death, serious deterioration in a person's state of health, or serious illness, that may require prompt remedial action, and that may cause significant morbidity or mortality in humans, or that is unusual or unexpected for the given place and time (Article 2 (68))
When to report (calendar/ working days)	Manufacturers shall report any serious incident immediately after they have established the causal relationship between that incident and their device or that such causal relationship is reasonably possible, and no later than 15 days after they have become aware of the incident (Article 87 (3)) In the event of a serious public health threat the report shall be provided immediately, and no later than 2 days after the manufacturer becomes aware of that threat (Article 87 (4)) In the event of death or unanticipated serious deterioration in a person's state of health the report shall be provided immediately after the manufacturer has established or as soon as it suspects a causal relationship between the device and the serious incident but no later than 10 days after the date on which the manufacturer becomes aware of the incident (Article 87 (5))
How (particular forms/ websites)	Article 33 – European database on medical devices – EUDAMED and Article 92 – Electronic system on vigilance and on post-market surveillance: a) the reports by manufacturers on serious incidents and field safety corrective actions referred to in Article 87(1) and Article 89(5); b) the periodic summary reports by manufacturers referred to in Article 87(9); c) the reports by manufacturers on trends referred to in Article 88; d) the periodic safety update reports referred to in Article 86; e) the field safety notices by manufacturers referred to in Article 89(8).
Why (reference)	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

Australia – Therapeutic Goods Association (TGA) (https://www.tga.gov.au) https://www.tga.gov.au/

Who reports	Manufacturers and/or the Australian Sponsor
What to report	Events must be reported by the manufacturer to the TGA, or to the Sponsor A serious threat to public health is an event or other occurrence, in relation to a kind of medical device, represents a serious threat to public health if: (a) the event or other occurrence is a hazard arising from a systematic failure of the device that becomes known to the person in relation to whom the device is included in the Register; and (b) the event or other occurrence may lead to the death of, or a serious injury to a patient, a user of the device or other person; and (c) the existence of, probable rate of occurrence of, or degree of severity of harm caused by, the hazard was not previously known or anticipated by the manufacturer of the device; and (d) the manufacturer will be required to take prompt action to eliminate, or reduce the risk of, the hazard. An adverse event is an event that led to: • death; • a serious injury or serious deterioration to a patient, user or other person, including a life-threatening illness or injury permanent impairment of a body function permanent damage to a body structure a condition necessitating medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure. A near adverse event is an event that might have led to a death or serious injury. For an event to be defined as a near adverse event, it is sufficient that: • an event associated with the device happened; • if the event occurred again, it might lead to death or serious injury; • testing or examination of the device or the information supplied with the device, or scientific literature indicated some factor that could lead to a death or serious injury.
When to report (calendar/ working days)	Serious threat to public health – 2 days An event that led to the death or serious deterioration in the state of health of a patient, user, or other person – 10 days An event that the recurrence of which might lead to the death or serious deterioration in the state of health of a patient, user, or other person – 30 days
How (particular forms/ websites)	IRIS (Incident Reporting & Investigation Scheme) for online reporting: https://apps.tga.gov.au/prod/mdir/mdirsummary.aspx MDIR (Medical Device Incident Reporting): https://tga.gov.au/reporting-adverse-events In addition: Class III, Class AIMD and Implantable Class IIb should have three consecutive annual reports submitted to the TGA following inclusion of the device in the Australian Registry of Therapeutic Goods (ARTG). Annual reports are due 1 October each year. Reports should be for the period 1 July to 30 June. The report is to include: • ARTG no. • Product name • # supplied in Australia and worldwide • Number of complaints in Australia and worldwide • Number of adverse events and incident rates in Australia and world wide • Regulatory/corrective action/notification by manufacturer
Why (reference)	Therapeutic Goods (Medical Devices) Regulations 2002 Schedule 3 Part 1 Clause 1.4(3)(c)(i)

Brazil – Agência Nacional de Vigilância Sanitária (ANVISA) (http://portal.anvisa.gov.br/contact-us)

Who reports	Manufacturers and the Brazilian Registration Holder must report to the Sistema Nacional de Vigilância Sanitária (SNVS)
What to report	The following events related to health products and involving patients, users or other persons: I – a serious threat to public health; II – death; III – serious adverse event that has not evolved to death; IV – technical complaint with the potential to cause death or serious adverse event; V – no severe adverse event; VI – technical complaint with the potential to cause no severe adverse event, and VII – fake (Counterfeit device).
When to report (calendar/ working days)	No later than 72 hours after first knowledge, the following events occur: a) death; b) serious threat to public health (serious threat to public health: any type of occurrence that results in an imminent risk of death, serious lesions or serious disease, that requires rapid corrective measures); c) forgery (Counterfeit device). No later than 10 calendar days after knowledge, the following events occur: a) serious adverse event, with no associated deaths; b) no severe adverse event, the recurrence has the potential to cause serious adverse event in patient, user or other person. No later than 30 calendar days after knowledge of a technically verified complaint which is associated with a health product registered in its name, which can lead to event adverse event in a patient, user or other person, provided that at least one of the following conditions be verified: a) the possibility of recurrence of the complaint technique is not remote; b) an occurrence of the same type has caused or contributed to death or serious damage to health in last 2 years; c) the holder of record of the product needs or need to take action to prevent imminent danger to health; d) there is possibility of error induced by use of design, labelling or poor instructions. No later than 10 (ten) calendar days after knowledge, the following events observed in other countries and associated with health product registered in its name in Brazil: a) death; b) serious threat to public health; c) forgery (Counterfeit device).
How (particular forms/ websites)	Tecnovigilância – National System of Sanitary Surveillance (SNVS) constituted by the Ministry of Health, National Health Surveillance Agency (ANVISA): http://portal.anvisa.gov.br/vigilancia-sanitaria-no-brasil* *Not published in English
Why (reference)	RDC ANVISA 67/2009 – Article 6, 7 and 8

Canada – Health Canada (http://www.hc-sc.gc.ca/dhp-mps/md-im/index-eng.php)

Who reports	Manufacturer and the Canadian Importer (unless the manufacturer provides the Minister written authorization to permit the importer to report on its behalf)
What to report	A mandatory problem report is required 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 labelling or in its directions for use; and • has led to the death or a serious deterioration in the state of health of a patient, user or other person, or could do so if it were to recur. *Note:* 'Sold' means 'Authorized for Sale' (for Class II, III, IV medical devices), i.e. reports should be submitted regardless of whether any units have yet been distributed. 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.
When to report (calendar/ working days)	(1) An event that led to the death or serious deterioration in the state of health of a patient, user or other person – 10 days: Serious deterioration in the state of health means a life-threatening disease, disorder or abnormal physical state, the permanent impairment of a body function or permanent damage to a body structure, or a condition that necessitates an unexpected medical or surgical intervention to prevent such a disease, disorder or abnormal physical state or permanent impairment or damage. *Note:* Serious deterioration in health also includes a serious public health threat which is any incident type, which results in imminent risk of death, serious deterioration in health or serious illness that requires prompt remedial action. (2) An event that the recurrence of which might lead to the death or serious deterioration in the state of health of a patient, user or other person – 30 days.
How (particular forms/ websites)	On line pdf form: http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/md-mm_form-eng.php Completed forms should be emailed to: mdpr@hc-sc.gc.ca or faxed to: 613-954-0941 or mailed to: Canada Vigilance – Medical Device Problem Reporting Marketed Health Products Directorate, Health Canada Address Locator 0701E 200 Tunney's Pasture Driveway Ottawa, Ontario K1A 0K9
Why (reference)	Medical Device Regulations SOR/98-282, Section 59-61

Japan – Ministry of Health, Labour and Welfare/Pharmaceuticals and Medical Devices Agency (https://www.pmda.go.jp/english/safety/info-services/drugs/medical-safety-information/0013.html)

Who reports	Market Authorization Holder
What to report	1) Death 2) Impediment 3) Case which has possibility of death or impediment 4) Hospital admission for curing or the case to extend admission period 5) Similar to ①–④serious cases 6) Congenital diseases in the later generation
When to report (calendar/ working days)	**Within 15 calendar days:** 1–6 **Within 30 calendar days:** 1–6 cases that could attribute to the effect of the malfunction of the medical devices; Other cases and infection diseases that could be attributed to the malfunction of the medical devices, or in addition, the user could not predict the cases from the IFU and precautions described in the container or the package.
How (particular forms/ websites)	Not published in English
Why (reference)	MHLW Ministerial Ordinance No. 135 [Good Vigilance Practice (GVP)] *Not published in English – Reference #8 – MHLW Ministerial Ordinance No. 135 of 2004 – referred to as 'GVP Ordinance'

USA – Food and Drug Administration (FDA)

https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/default.htm

Who reports	Manufacturers or importers
What to report	Death, or serious injury, which means an injury or illness that: • is life threatening; • results in permanent damage to a body structure; • results in permanent impairment of a body function. (Permanent means irreversible, but not trivial, impairment or damage to a body structure or function.) An injury or illness that necessitates medical or surgical intervention to preclude permanent damage to a body structure or permanent impairment of a body function. A device malfunction (or failure to meet performance specifications or otherwise perform as intended) such that the device or a similar device would be likely to cause a death or serious injury if the malfunction were to recur. Performance specifications include all claims made in the labelling for the device. Intended use may be shown by labelling claims; advertising matter; oral or written statements. A malfunction is considered likely to cause or contribute to a death or serious injury if: • the chance of it causing such an event is not remote or minute; • it affects the device in a catastrophic manner that may lead to a death or serious injury; • the manufacturer takes or would be required to take action to prevent a hazard to health as a result of the malfunction; • a malfunction of the same type has actually caused or contributed to a death or serious injury in the past 2 years.
When to report (calendar/ working days)	Adverse event report: the time from the date the manufacturer or user facility became aware of information that reasonably suggests that a device has or may have caused or contributed to the event to the date of the report. • Manufacturer: Death, serious injury, reportable malfunctions: to FDA within 30 calendar days. • User facility: Death should be notified to FDA and the manufacturer within 10 working days. Serious injury should be notified to the manufacturer within 10 working days. (reports to FDA if device manufacturer is not known). • Distributor should notify manufacturer of reports of death, serious injury, and malfunctions within 10 working days. Death and serious injuries should be notified to the FDA within 10 working days. *Manufacturer 5-day report*: the time runs (in working days) from the manufacturer became aware that a reportable MDR event necessitated remedial action to prevent an unreasonable risk of substantial harm to the public health to the date of the report; or becoming aware of a reportable event for which FDA has made a written request for the submission of a 5-day report. When such a request is made, the manufacturer shall submit, without further requests, a 5-day report of all subsequent events of the same nature that involve substantially similar devices for the time period specified in the written request. *5-day manufacturer report means a report submitted upon:* becoming aware that a reportable event or events, necessitates remedial action to prevent an unreasonable risk of substantial harm to public health;or becoming aware of a reportable event for which FDA has made a written request for the submission of a 5-day report. When such a request is made, the manufacturer shall submit, without further requests, a 5-day report for all subsequent events of the same nature that involve substantially similar devices for the time period specified in the written request.

How (particular forms/ websites)	Mandatory adverse event report (MedWatch Form 3500A) for manufacturers, user facilities and importers: http://www.fda.gov/ForIndustry/FDAeSubmitter/default.htm
Why (reference)	Submit reports of MDR reportable events involving their medical devices [21 CFR 803.10(c) and 803.50]. Develop, maintain and implement written procedures for the identification and evaluation of all adverse medical device events to determine whether the event is an MDR reportable event [21 CFR 803.17]. Establish and maintain complete files for all complaints concerning adverse medical device events [21 CFR 803.18].

Contributors

BSI is grateful for the help of the following people in the development of the white paper series

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Published white papers

The Proposed EU Regulations for Medical and In Vitro Diagnostic Devices: An Overview of the Likely Outcomes and Consequences for the Market, Gert Bos and Erik Vollebregt

Generating Clinical Evaluation Reports – A Guide to Effectively Analysing Medical Device Safety and Performance, Hassan Achakri, Peter Fennema and Itoro Udofia

Effective Post-market Surveillance – Understanding and Conducting Vigilance and Post-market Clinical Follow-up, Ibim Tariah and Rebecca Pine

What You Need to Know About the FDA's UDI System Final Rule, Jay Crowley and Amy Fowler

Engaging Stakeholders in the Home Medical Device Market: Delivering Personalized and Integrated Care, Kristin Bayer, Laura Mitchell, Sharmila Gardner and Rebecca Pine

Negotiating the Innovation and Regulatory Conundrum, Mike Schmidt and Jon Sherman

The Growing Role of Human Factors and Usability Engineering for Medical Devices: What's Required in the New Regulatory Landscape? Bob North

ISO 13485: The Proposed Changes and What They Mean for You, Bill Enos and Mark Swanson

The Differences and Similarities between ISO 9001 and ISO 13485, Mark Swanson

How to Prepare for and Implement the Upcoming MDR: Dos and Don'ts, Gert Bos and Erik Vollebregt

How to Prepare for and Implement the Upcoming IVDR: Dos and Don'ts, Gert Bos and Erik Vollebregt

Planning for Implementation of the European Union Medical Devices Regulations – Are you prepared?, Eamonn Hoxey

Cybersecurity of Medical Devices, Richard Piggin

The European Medical Devices Regulations – what are the requirements for vigilance reporting and post-market surveillance?, Eamonn Hoxey

General Safety and Performance Requirements (Annex 1) in the New Medical Device Regulation – Comparison with the Essential Requirements of the Medical Device Directive and Active Implantable Device Directive, Laurel Macomber and Alexandra Schroeder.

Forthcoming white papers

Clinical Data – Moving away from Clinical Equivalence in Europe (working title)

Modifying, Creating and Maintaining Technical Documentation (working title)

Managing changes to a QMS (working title)

Nanotechnology – what does the future look like for the medical devices industry? (working title)

About BSI Group

BSI (British Standards Institution) is the business standards company that equips businesses with the necessary solutions to turn standards of best practice into habits of excellence. Formed in 1901, BSI was the world's first National Standards Body and a founding member of the International Organization for Standardization (ISO). Over a century later it continues to facilitate business improvement across the globe by helping its clients drive performance, manage risk and grow sustainably through the adoption of international management systems standards, many of which BSI originated. Renowned for its marks of excellence including the consumer recognized BSI Kitemark™, BSI's influence spans multiple sectors including aerospace, construction, energy, engineering, finance, healthcare, IT and retail. With over 70,000 clients in 150 countries, BSI is an organization whose standards inspire excellence across the globe.

BSI is keen to hear your views on this paper, or for further information please contact us here:
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This paper was published by BSI Standards Ltd

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