Australian Government
Department of Health
Therapeutic Goods Administration

Proposed enhancements to adverse event reporting for medical devices

Consultation paper

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TGA Health Safety Regulation

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Introduction

Compliance by the medical device industry with regulatory requirements for medical devices in Australia is never optional. The obligations are based on globally aligned requirements including the ongoing monitoring of the safety and performance of medical devices after they have been approved and made available to Australian patients.

However, more could be done to strengthen the way the Therapeutic Goods Administration (TGA) undertakes its post market surveillance of medical devices to identify issues with medical devices faster and to make more information available about these issues to users of medical devices, their families and healthcare professionals.

Aim of a post market monitoring system

The aim of a post-market monitoring and vigilance system for medical devices is to maintain the safety of patients and, through the collection, analysis, and action taken in response to adverse event reports, reduce the likelihood of adverse events recurring. Adverse event reporting allows the TGA to monitor medical device performance in the real world and identify emerging safety and performance issues.

Individual reports are reviewed, risk assessed, and followed-up to ascertain the level of harm experienced, the threat to others from use of the same or similar devices, the likelihood of recurrence, and the actions that may need to be undertaken. Investigations into adverse event reports are prioritised according to the severity or potential of harm, frequency of similar reported incidents, and the root cause. The TGA then takes action to mitigate or resolve ongoing risks, where appropriate.

Despite these activities, there have been hazards associated with medical devices that if identified and mitigated earlier could have prevented further harm.

Reviews that have called for enhancements and improvements

A number of reviews and inquiries have highlighted the safety of medical devices and the process for monitoring them once supplied on the market. While Australian regulatory practices are comparable to other regulators around the world, this consultation seeks feedback on proposals to strengthen them further. Improving Australia's adverse event reporting system will more promptly address threats to patient safety and to take quicker action.

The ***Expert Panel Review of Medicines and Medical Devices Regulation (MMDR)*** recommendations accepted by the Government in 2016 proposed that the TGA could improve post-market monitoring by:

- Capturing more data on adverse events and other incidents;
- Adopting a more systematic and transparent approach to risk assessment of adverse event and incident reports;
- Enhancing methods of identifying cases that require further investigation;
- Strengthening prioritisation of cases for investigation; and
- Identifying major improvements to the quality and safety of medical devices.

The 2018 ***Senate Committee Inquiry*** into the 'Number of women in Australia who have had transvaginal mesh implants and related matters', recommended providing increased information about the medical devices to patients, improved post-market vigilance and adverse event reporting, including mandatory reporting of adverse events by surgeons.

An Action Plan for Medical Devices, released in 2019, outlined the commitment of the TGA to undertake consultation on a number of initiatives. The Action Plan builds on the Government's commitment to implement the recommendations of previous reviews and inquiries to strengthen Australia's regulatory system and putting the safety of Australian patient first. The Action Plan comprises of three strategies:

- Strategy 1: Improve how new devices get on the market
- Strategy 2: Strengthen monitoring and follow up of devices already in use
- Strategy 3: Provide more information to patients about the devices they use.

Actions taken to date

The TGA has already made a number of changes to strengthen the post-market monitoring and vigilance of medical devices. These include:

- Requiring sponsors of certain high-risk devices to provide more frequent adverse event reports to the TGA.
- Changing our online adverse event reporting forms to make it simpler for consumers and healthcare professionals to report.
- Consulting on introducing a unique medical device identification system in Australia, assisting more accurate reporting and efficient analysis of adverse events, recalls, and better international device information sharing.
- Implementing new risk analysis tools and improved data analytics for early signal detection.
- Actively engaging consumer groups, healthcare professionals and hospitals to explain the system, improve awareness, and encourage increased adverse event reporting.
- Co-leading an Australian Health Ministers Advisory Council project to identify ways for rapid information sharing between states, territories and the TGA.
- Undertaking targeted consultation with stakeholders to identify additional ways to improve data collection and sharing between the TGA and hospital systems.

Purpose of this consultation

The focus of this consultation paper is to seek feedback on five proposals.

Our proposals aim to improve access to information about medical device safety. In addition to making it easier to report problems with a medical device, information about known or suspected problems with devices must be accessible and be understood by consumers, their families and their health professionals. In particular:

- the risks or problems relating to either a specific medical device or a broad type of medical device;
- how patients might be affected by these medical devices;

- how the harm might or has already occurred; and
- what to do if there are concerns.

We are seeking feedback on five proposals to make changes in relation to safety information, including adverse event reports and recall information, and ways to improve the accessibility and usability of this information.

The five proposals are:

Proposal 1 – make changes to the current adverse event reporting exemptions;

Proposal 2 - strengthen reporting requirements for medical device adverse events;

Proposal 3 - implement a program of TGA inspections and audits of sponsor activities and premises to validate how they conduct their post market surveillance obligations;

Proposal 4 - review post-market definitions in the Medical Device Regulations; and

Proposal 5 – find ways to enhance communication between the TGA and the consumers of medical devices.

NOTE: Further consultations

The TGA will undertake further consultations during 2020-21 on proposed initiatives to further improve post-market monitoring and vigilance of medical devices, including in vitro diagnostic (IVD) devices. These are:

1. Proposed alignment with the European Union medical device regulatory framework for periodic safety update reporting;
2. The design of a medical device Unique Device Identification (UDI) system; and
3. The feasibility of mandatory adverse event reporting by healthcare facilities.

Background

What is a medical device?

There is a legal definition for a medical device, but generally, the term medical device refers to products or equipment that have a physical or mechanical effect on the body or is used to measure (or monitor) the body and its functions.

These devices represent a wide range of products, from tongue depressors, medical gloves, bandages, syringes, blood pressure monitors, and hospital beds, through to implantable pacemakers, ventilators, and the latest types of high technology diagnostic and treatment machines. In vitro diagnostic (IVD) devices, such as pregnancy tests and glucose meters, are also medical devices.

How are medical devices regulated?

All medical devices supplied in Australia, unless exempt, must first be approved by the TGA and included in the Australian Register of Therapeutic Goods (ARTG). Requirements for inclusion varies according to the level of risk associated with each device. Every device must have an Australian sponsor (i.e.: an organisation or person who has the legal responsibility for the device in Australia). Following inclusion, the TGA has an ongoing role in monitoring compliance with quality, performance, and safety requirements for these devices. Australia's regulatory requirements are set out in the *Therapeutic Goods Act 1989* and the Therapeutic Goods (Medical Device) Regulations 2002, which mandate the product manufacturers and/or sponsors to report medical device incidents (adverse events) to the TGA. While health professionals and consumers are also strongly encouraged to report, this is done voluntarily and is not mandated.

The TGA investigate medical device incident reports to determine their impact, risk, underlying cause, and any actions that may be required to protect the ongoing safety of Australians.

In 2019, the TGA received 5,995 medical device adverse event reports, of which sponsors of the medical device reported the vast majority (approximately 84%). Although the number of reported medical device incidents has been steadily increasing over the past years, it is evident that a very significant number are not reported to the TGA. This may be because patients or health professionals are unaware that they can report incidents directly to the TGA; or the incidents are reported to other parties, such as hospitals, who may / may not report the incident to the TGA, sponsor, or manufacturer of the device.

The *Therapeutic Goods Act 1989* ('the Act') and the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Regulations) specify the legal definition of a medical device and the requirements for the regulation of medical devices which includes IVD devices, in Australia.

What is a medical device adverse event?

A medical device adverse event is an event that led to:

- death; or
- a serious injury or serious deterioration to the health of 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; or
  - 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. It may be that due to timely intervention of a healthcare practitioner, a death or serious injury did not occur.

Medical device incident reporting by sponsors, including both adverse events and near adverse events, allows the TGA to monitor medical device performance and identify emerging safety issues. These vigilance activities enable us to take timely and appropriate regulatory action.

Failure by the sponsor to report adverse events or near adverse events within the relevant timeframes may lead to suspension or cancellation of the device from the ARTG (section 41G of the Act). In some instances, failure to meet these requirements may constitute a criminal and/or civil offence (section 41MN of the Act).

Adverse event reporting criteria

Adverse event reporting is mandatory for sponsors.

Medical device incidents need to meet three criteria to require reporting to the TGA. These are:

- An adverse event has occurred, or had the potential to occur;
- The medical device is associated with the adverse event; and
- The event led to or might lead to death or serious injury.

Examples of reportable adverse events that affect a patient or user are:

- An orthopaedic implant prematurely fails resulting in the need for revision surgery.
- An infusion pump stops, due to a malfunction, but fails to give an alarm; a nurse notices the malfunction in time to prevent permanent injury to the patient.
- A blood glucose meter gives false high/low result leading to treatment change.

Examples of reportable adverse events that raise broader public health issues include, if:

- Fatigue testing performed on a heart valve bio-prosthesis demonstrates premature failure, which would indicate that a risk to public health could occur.
- A review determines that the Instructions for Use (IFU) for a reusable surgical instrument used in brain surgery provide insufficient details on cleaning methods, therefore increasing the risk of transmission of Creutzfeldt-Jakob Disease (CJD).
- Events that may be associated with cybersecurity or data loss including any breach, vulnerability, exploit, threat and risk.

Consultation on proposed changes

Proposal 1: Make changes to the current adverse event reporting exemptions

For your information

Current exemption rules	Situations when the exemption rules DO NOT apply
Currently there are eight exemption rules listed in the Australian Regulatory Guidelines for Medical Devices (ARGMD)[1] that may exempt sponsors from reporting an adverse event. These exemptions rules are: 1. The deficiency of a new device was found by the user prior to its use. 2. An adverse event was caused solely by patient conditions. 3. The device had exceeded its service life and the failure mode was not unusual. 4. A design feature protected against a fault becoming a hazardous situation. 5. The device was known to have a remote likelihood of occurrence of death or serious injury. 6. The event was an expected and foreseeable side effect that is documented in the manufacturer's IFU or labelling. 7. The events occurred after the manufacturer had issued an advisory notice. 8. Reporting exemptions have been granted by the TGA for this particular kind of event.	Following are the circumstances when the exemption rules cannot be applied: 1. The TGA may specifically identify that a device, event, or issue requires close monitoring. 2. There is a change in trend (usually an increase in frequency of reporting) or a pattern is identified in an event that is normally subject to a reporting exemption. 3. An adverse event is associated with user error. 4. Corrective action has been identified as necessary for a device. 5. Revision are made to product labelling or product IFU. 6. A need for increased user education is identified.

[1] ARGMD -Adverse event exemption rules

The problem

Exemption rules in Australia are consistent with exemption rules in other comparable countries. However, exemptions from reporting might be one of the reasons for lower than expected adverse event reporting as these rules could be misinterpreted, resulting in missed opportunities for timely detection and appropriate action against an adverse event. Whilst the ARGMD states that '*if a manufacturer believes an exemption rule applies to reporting an adverse event, the reasons for not reporting the event should be documented*', there have been inconsistencies identified in the methods of recoding the decision making process undertaken for not reporting an adverse event.

Options

We are seeking feedback on the following three proposed options for enhancing adverse event reporting:

1. Removing all exemption rules for reporting medical device adverse events; or
2. Removing some of the exemption rules that have been misinterpreted in past; and/or
3. Rewording some of the exemption rules and simplifying jargon along with providing examples to illustrate the application of the exemption rule.

Consultation question

Should the exemption rules for reporting medical device adverse events be changed? Which option/s are preferred and why?

If not, then do you have alternative modifications to propose?

Proposal 2: Strengthen reporting requirements for medical device adverse events

For your information

Currently, medical device adverse event reporting is mandatory for manufacturers and sponsors.

Reporting timeframes: The Regulations require medical device sponsors to report adverse events within mandatory timeframes depending on the severity of the incident. The mandatory timeframes to report an adverse event are:

- If it represents a serious threat to public health – 48 hours after the person became aware of the event or occurrence;
- The event or other occurrence led to the death, or serious deterioration in the state of health of a person – 10 days; and
- The event or other occurrences might have led to death or a serious deterioration in the state of health of a patient, a user of the device, or another person - 30 days

Sponsors may submit an initial report with all the available details within these timeframes and then provide further information as it becomes available through a follow-up and final report. The *Medical Device Incident Reporting (MDIR) guide – Sponsor guide to MDIR 2019* provides guidance on medical device incident reporting.

Device information: An ARTG entry can include many models of medical devices (generally identified through a unique product identifier – UPI). These medical devices under a single ARTG entry must have the same manufacturer, sponsor, device classification, nomenclature system code, and intended purpose. The ability of the TGA to efficiently understand which models of device are included in an ARTG entry, the functionality of a device, or if complications that have occurred are known to the manufacturer during risk assessment increases if an IFU is provided to the TGA with the submission of the adverse event report.

The problem

Currently, whilst the legislation provides the timeframe for an initial report, it does not include a mandated timeframe to submit the final adverse event report. This has resulted in delays to commencing an investigation, identifying trends, or withdrawing a medical device in a timely manner.

The ARGMD outlines that the supply data and similar event data are to be included in an adverse event report. However, this is often not provided by the sponsor in the initial or the follow up report. Moreover, analysing this data and identifying trends is currently difficult due to inconsistencies in format of data collection and unavailability of an IFU associated with the medical device.

Options

We are seeking feedback on the following proposed options for enhancing reporting requirements for adverse events related to medical devices (several could be simultaneously implemented):

1. A final report could be required to be submitted within a specific time period; for example, within 90 days of the initial adverse event report.
2. Requiring the final adverse event report to include the IFU, supply data and similar adverse event data for the particular device.
3. The provision of data and documents to the TGA via an online form and in a specified format to facilitate effective data analyses.

Consultation question

Should the medical device adverse event reporting requirements be enhanced by the implementation of some, or all, of the options provided?

If not, then do you have an alternative course of action to propose?

Proposal 3: Implement a program of TGA inspections and audits of sponsor activities and premises

For your information

Currently, it is a condition of inclusion for a medical device in the ARTG that the TGA may inspect a limited number of documents held by a sponsor on their or any other related premises. These documents include:

- Evidence of the relationship between the sponsor and manufacturer of the medical device;
- Supply details of the medical device; and
- Any adverse event reports, complaints, and recalls actions.

There are substantial benefits in inspecting a sponsor premises as this may assist in improving processes and providing regulatory insights for sponsors in relation to their adverse event reporting documentation and practises. The inspection may highlight where changes to the sponsor adverse event reporting systems could occur if any gaps were identified; ultimately ensuring the ongoing safety of medical devices available for the Australian communities.

The problem

Currently, the TGA undertakes a pharmacovigilance program for medicines, including sponsor premise inspections. However, for medical devices there is no comparable program in place where inspections of sponsors' premises are routinely undertaken.

Options

We are seeking feedback on the following options to implement an inspection program:

- Implement an on-site audit program to verify sponsors are complying with the conditions of inclusion in the ARTG, such as possessing an agreement with the manufacturer, appropriate collection of distribution data, and recording of complaints, adverse events, and recall actions.
- Implement a virtual education program to assist the sponsors, whilst promoting best practice regulatory compliance to ensure end user safety.

Consultation questions

Should the TGA implement both an on-site audit and education program relating to sponsors' premises and activities?

Is an education and assistance program to promote best practice regulatory compliance the optimal approach or are there better approaches?

Proposal 4: Review post-market definitions in the Medical Device Regulations

For your information

The European Union (EU) Regulation on Medical Devices (2017/745) introduced several amended post-market related definitions. These amended definitions will be adopted in each member states / European countries legislative instruments. We have provided an overview of the EU amended definitions and reference to the definitions/terminology used in the Australian legislation. For a detailed comparison, please refer to **Attachment G: Table 9**.

EU Regulations on Medical Devices (2017/745)	Australian legislation and regulations
(57) 'adverse event'	No definition of adverse event, although section 41MP(2) provides an implied definition
(60) 'post-market surveillance'	Comparable definition is provided in each of the conformity assessment procedures of the Regulations
(66) 'serious public health threat'	Comparable definition is provided in the Regulations under Division 5.2 - Conditions, Regulation 5.7 - Conditions applying automatically—period for giving information about adverse events etc.
(61) 'market surveillance' (64) 'incident' (65) 'serious incident' and (58) 'serious adverse event'	No equivalent definition.

The problem

If there is global inconsistency between legal requirements for how adverse events are reported, this makes it difficult and time consuming for sponsors / manufacturers and regulators to share information and act quickly on adverse event information. If there is limited alignment between the risk and severity in which a device incident is defined, this could create confusion as to the most appropriate response time for action.

Options

It may be considered that most of these words/terminology are self-explanatory and/or have already established meaning in the Australian setting. Providing definitions for these words in the guidance on post-market expectations for sponsors and manufacturers may be an alternative to legislative changes. We are seeking feedback on the following options:

- To **not adopt** the EU definitions; or
- To adopt some of the EU definitions into the Australian Regulations; or
- To adopt all the EU definitions into the Australian Regulations; or
- To adopt the EU definitions into the Australian Guidance materials.

Consultation questions

Should the new EU adverse event definitions (as above) be included in the Australian Regulations and/or Guidance documentation?

Are there substantial benefits of including definition of these words or are they self-explanatory?

Proposal 5: Find ways to enhance communication between the TGA and the consumers of medical devices

For your information

We currently publish up to date information about medical devices including incident reports, subsequent regulatory actions, and recall actions on the TGA website.

How the TGA communicates important information to the end users?

Adverse event reports	Adverse events reports received by the TGA can be accessed through a searchable database: Database of Adverse Event Notifications (DAEN)
Recall actions	Information on the medical device recall actions can be accessed through TGA's database: System for Australian Recall Actions (SARA)
Alerts	The TGA publishes regular alerts about therapeutic goods on its website
Social media	TGA's Facebook, LinkedIn, Twitter, YouTube, Instagram

The problem

Feedback from consumer groups has confirmed that most consumers do not know about or understand the role of the TGA, or the provision of information about medical devices incidents. Those consumers that do know about the TGA, find the information provided is difficult to navigate and hard to understand due to use of jargon or technical / regulatory words. Most health professionals who use medical devices understand the role of the TGA but have limited interaction, including reporting any incidents about a medical device.

Options

To enhance our support of patient safety, information about known or suspected problems with medical devices must be accessible and in a format that is usable by health professionals, medical device users, patients, and other stakeholders. This includes information that can be easily and quickly accessible by hospital purchasing and/or safety committees. We are seeking feedback on how we can improve our communication with consumers of medical devices – including patients, health professionals, hospitals, purchasers and other stakeholders. We are seeking feedback on how the TGA can enhance the communication with consumers and the material and information provided. Feedback on specific areas on our website or references to existing materials would be welcomed. This includes referring back to the list of published information links above or to our device specific hubs (e.g. mesh hub) or focused website questions and answers (e.g. breast implants).

Consultation questions

Please provide feedback on whether or not the TGA is effectively communicating the issues related to medical devices based on:

- Availability
- Applicability
- Accessibility
- Useability

Please provide your suggestions on how the TGA can improve communication about the medical device incident related information to the end users?

Attachment G

Table 9: detailed comparison between the amended definitions in EU Regulations and the definitions/terminology used in the Australian Legislation and regulations

EU Regulation on Medical devices (2017/745)	Australian legislation and regulations
(57) 'adverse event' means any untoward medical occurrence, unintended disease or injury or any untoward clinical signs, including an abnormal laboratory finding, in subjects, users or other persons, in the context of a clinical investigation, whether or not related to the investigational device;	There is no definition of adverse event in the Act, although section 41MP(2) provides an indirect definition: (2) The information with which subsection (1) is concerned is information of the following kinds: (a) information relating to: (i) any malfunction or deterioration in the characteristics or performance of the kind of device; or (ii) any inadequacy in the design, production, labelling, IFU or advertising materials of the kind of device; or (iii) any use in accordance with, or contrary to, the use intended by the manufacturer of the kind of device; that might lead, or might have led, to the death of a patient or a user of the device, or to a serious deterioration in his or her state of health; (b) information relating to any technical or medical reason for a malfunction or deterioration of a kind referred to in subparagraph (a)(i) that has led the manufacturer to take steps to recall devices of that kind that have been distributed; (c) information that indicates that a device of that kind does not comply with the essential principles; (d) information that indicates that a certificate or other document (other than a certificate or other document issued by the Secretary under this Act) used for the purpose of an application under subsection 41FC (1) to signify: a. compliance with the essential principles; or b. the application of relevant conformity assessment procedures to a device of that kind or the application of requirements, comparable to those procedures, to a device of that kind;

EU Regulation on Medical devices (2017/745)	Australian legislation and regulations
(58) 'serious adverse event' means any adverse event that led to any of the following: a) death, b) serious deterioration in the health of the subject, that resulted in any of the following: i. life-threatening illness or injury, ii. permanent impairment of a body structure or a body function, iii. hospitalisation or prolongation of patient hospitalisation, iv. medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function, v. chronic disease, foetal distress, foetal death or a congenital physical or mental impairment or birth defect;	No equivalent definition.
(60) 'post-market surveillance' means all activities carried out by manufacturers in cooperation with other economic operators to institute and keep up to date a systematic procedure to proactively collect and review experience gained from devices they place on the market, make available on the market or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions	Comparable definition is provided in each of the conformity assessment procedures of the Regulations, for example, under Part 6 – Declaration of conformity (not requiring assessment by Secretary) procedures, clause 6.5: 1. The manufacturer of a medical device to which technical documentation prepared under clause 6.4 of this Schedule applies must establish, and keep up to date, a post marketing system that complies with subclause (2) for use in relation to devices of that kind. 2. A post marketing system complies with this subclause in relation to a medical device if the system requires the manufacturer of the device: a. to systematically review experience gained in the post production phase in relation to medical devices of that kind; and b. to implement appropriate means to apply any necessary corrective action in relation to the design or production of such devices; and c. to notify the Secretary, or the person in relation to whom the kind of device is included in the Register, as soon as practicable after becoming aware of: (i) information relating to: A. any malfunction or deterioration in the characteristics or performance of the kind of device; or

EU Regulation on Medical devices (2017/745)	Australian legislation and regulations
	B. any inadequacy in the design, production, labelling, IFU or advertising materials of the kind of device; or C. any use in accordance with, or contrary to, the use intended by the manufacturer of the kind of device; that might lead, or might have led, to the death of a patient or a user of the device, or to a serious deterioration in his or her state of health; or (ii) information relating to any technical or medical reason for a malfunction or deterioration of a kind mentioned in subparagraph (i) that has led the manufacturer to take steps to recall devices of that kind that have been distributed. Note: See also paragraph 41FN(3)(d) and section 41MP of the Act in relation to the requirement to give certain information about a medical device to the Secretary.
(61) 'market surveillance' means the activities carried out and measures taken by competent authorities to check and ensure that devices comply with the requirements set out in the relevant Union harmonisation legislation and do not endanger health, safety or any other aspect of public interest protection.	No equivalent definition.
(64) '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.	No equivalent definition.
(65) 'serious incident' means any incident that directly or indirectly led, might have led or might lead to any of the following: a) the death of a patient, user or other person b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health, c) a serious public health threat.	No equivalent definition.

EU Regulation on Medical devices (2017/745)	Australian legislation and regulations
(66) 'serious public health threat' means an 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.	Comparable definition is provided in the Regulations under Division 5.2 - Conditions, Regulation 5.7 - Conditions applying automatically—period for giving information about adverse events etc. (also see section 41FN of the Act). (2) For paragraph (1)(a), 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 another 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.

Version history

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