From: s22
To: s22
Cc: s22
Subject: RE: Four Corners story on chronic pain and SCS [SEC=OFFICIAL]
Date: Thursday, 11 April 2024 5:05:50 PM
Attachments: image001.png
image002.png
image004.png
image005.png

Dear s22 ,

Thank you for getting in touch with us about the recent media. Please accept my apologies for the delay in responding.

Your submission is currently under review and we will be in touch if we need further clarification, and will let you know if we think a meeting will be helpful.

Whilst the TGA considers all signals and information available from a number of sources, for sources that are material to a decision, a sponsor will have the opportunity to review and reply to such information.

Best regards,
s22

s22
A/g Director
Devices Post Market Reviews Section
Medical Devices Surveillance Branch

Phone: s22
Email: s22 @health.gov.au

Therapeutic Goods Administration
Department of Health and Aged Care
PO Box 100
Woden ACT 2606
www.tga.gov.au

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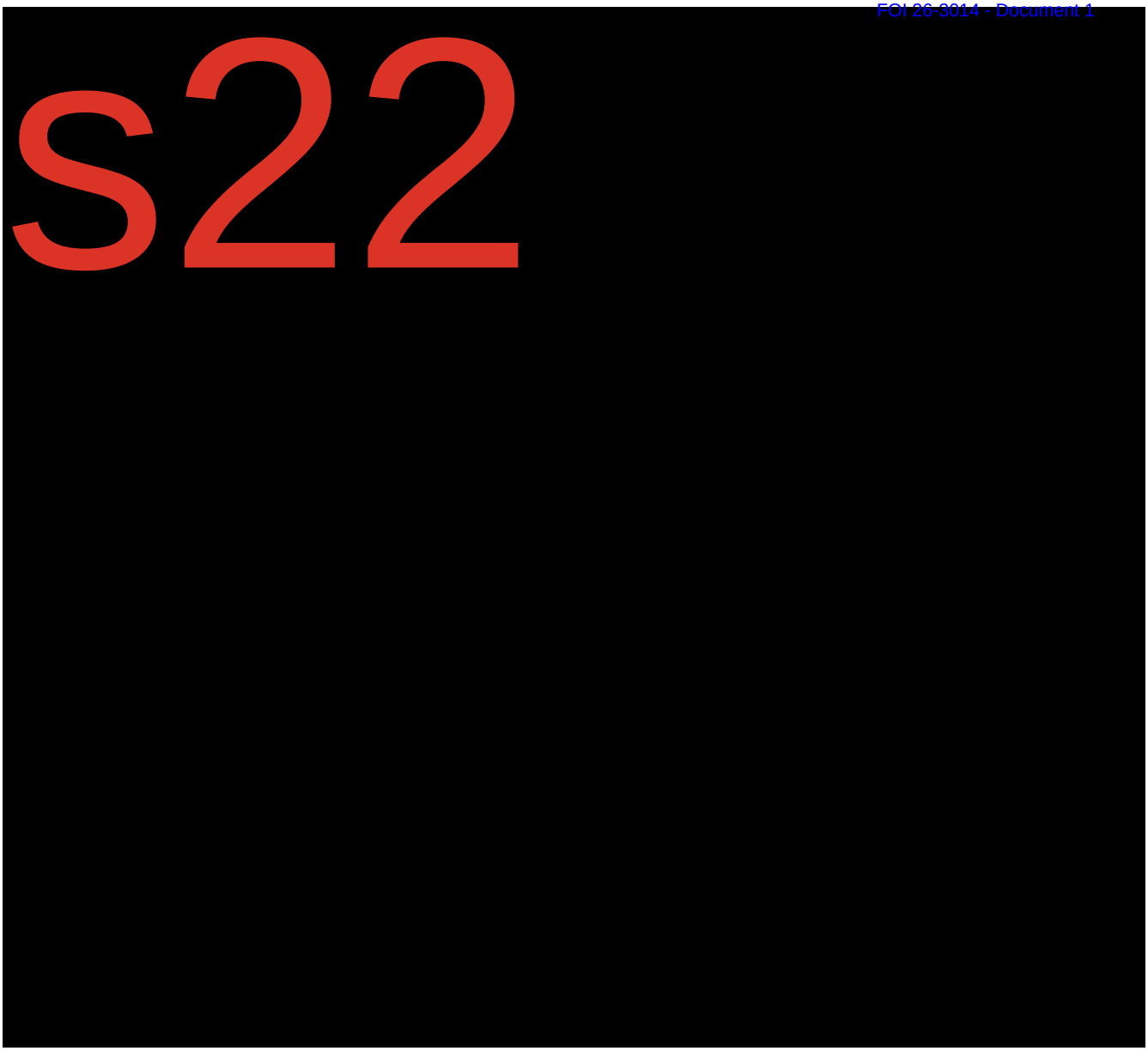
s22

s22



From: IRIS
To: s22
Subject: s45 AB Letter Notice on Complaints and Adverse Events [SEC=OFFICIAL, ACCESS=Personal-Privacy]
Date: Wednesday, 8 May 2024 2:25:36 PM
Attachments: image001.png
Medtronic Australasia Pty Ltd -s45 AB Notice on complaints and adverse events - SCS.PDF

Dear s22 ,

Please see the attached s45 AB letter in relation to spinal cord stimulator devices. Please provide the required documents by **COB 07 June 2024.** The information can be submitted to IRIS@health.gov.au.

Kind Regards,

s22
Administration Officer

Devices Post Market Monitoring Section | Medical Devices Surveillance Branch
Australian Government, Department of Health and Aged Care
Therapeutic Goods Administration

Medical Device and Product Quality Division | Health Products Regulation Group
Medical Devices Surveillance Branch
Australian Government, Department of Health and Aged Care
T: s22 | E: s22
Location: Melbourne Office
PO Box 100, Woden ACT 2606, Australia
www.tga.gov.au

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

s22
Medtronic Australasia Pty Ltd
s22
[redacted]
[redacted]
[redacted]

Our Reference: E24-185354
Sent by email

Dear s22

Subject: SECTION 45AB NOTICE GIVEN TO METRONIC AUSTRALASIA PTY LTD

PART A – Details of the notice

1. I am writing to the Sponsor, in my capacity as a delegate of the Secretary for the purpose of section 45AB of the Act.
2. I have decided to give the Sponsor a written notice under subsection 45AB(1) of the Act, requiring the Sponsor to give to the Secretary the information, and produce to the Secretary the documents, specified in Part D and Part E below.
3. The Sponsor is required to comply with this notice by 7 June 2024.
4. The information and documents are relevant to contraventions or possible contraventions of subsection 41MPA(1) or 41MNA(1) of the Act by the Sponsor. The details of the contraventions or possible contraventions are as follows:
    a. The Sponsor is, and at all relevant times was, the person in relation to whom the Devices are, and were, included in the ARTG. The Devices are spinal cord stimulators or related medical devices.
    b. A comparison of information provided to the TGA by the Sponsor as provided in the investigation PMR-2022-01814 concerning the number of adverse event or complaints concerning the Devices collected by the Sponsor about the Devices,[1] and the number of DIRs reported to the TGA by the Sponsor in relation to the Devices, indicates possible under-reporting of Adverse Event Information to the TGA.
    c. Additionally recent reporting by the Australian Broadcasting Corporation appears to allege systemic and '…*vast under-reporting of adverse*

[1] Provided as part of the current post-market review investigation of spinal cord stimulators under PMR-2022-01812: https://www.tga.gov.au/how-we-regulate/supply-therapeutic-good/supply-medical-device/medical-device-post-market-reviews/post-market-review-spinal-cord-stimulation-scs-devices.

impacts of [spinal cord] *stimulators in the TGA's database*',[2] which may include under-reporting by the Sponsor.

d. If the Sponsor did not notify the Secretary of particular information which was Adverse Event Information relating to a Device within the period specified in regulation 5.7 of the Medical Devices Regulations, the Sponsor possibly contravened or did contravene:

    i. subsection 41MPA(1) of the Act,[3] and committed, or possibly committed, a separation contravention on each day (after the period specified in regulation 5.7) that the Secretary was not notified;[4]

    ii. by its omission, subsection 41MNA(1) of the Act, because the omission breached the COI contained in paragraph 41FN(3)(d) of the Act.

e. The inclusion of the Devices in the ARTG is, and at all material times was, subject to the COI contained in paragraph 41FN(3)(b) of the Act, which required that the Sponsor have available sufficient information to substantiate that the CAPs had been applied to the Devices, or procedures in place, including a written agreement with the Manufacturer, to ensure that such information could be obtained within 20 working days.

f. If the Sponsor does not, or at any material time did not, have available sufficient information to substantiate that the CAPs had been applied to the Devices (and cannot, or could not, obtain that information from the Manufacturer within 20 working days), the Sponsor possibly contravened, or did contravene, subsection 41MNA(1) of the Act.

g. The inclusion of the Devices in the ARTG is, and at all material times was, subject to the COI contained in paragraph 41FN(3)(e) of the Act[5], which required the Sponsor to give the Manufacturer information relevant to:

    i. the Manufacturer's obligations under the CAPs, including Adverse Event Information and Complaint Information; and

    ii. whether medical devices of a relevant kind comply with the Essential Principles.

h. If the Sponsor did not at all material times give the Manufacturer information relevant to paragraphs 4.g.i or 4.g.ii above, the Sponsor possibly contravened, or did contravene, subsection 41MNA(1) of the Act.

---

[2] See 29 April 2024 article at https://www.abc.net.au/news/2024-04-29/calls-for-action-on-spinal-cord-stimulators/103776134. See also the Four Corners program titled 'Pain Factory' published on or around 8 April 2024.

[3] The period in regulation 5.7 being prescribed in regulation 10.4AA in relation to paragraph 41MPA(1)(c).

[4] Section 42YCA of the Act.

[5] With information required for the purposes of paragraph 41FN(3)(e) of the Act being particularised in reg 5.8 of the Medical Devices Regulations, as made under subsection 41FN(4) of the Act.

PART B – Definitions

5. In the notice, unless the contrary intention appears:
    a. the **Act** means the *Therapeutic Goods Act 1989*.
    b. **Adverse Event Information** means information of a kind mentioned in subsection 41MP(2) or 41MPA(2) of the Act, namely:
        (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, instructions for use 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 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:
            (i) compliance with the essential principles; or
            (ii) 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;

        has been restricted, suspended, revoked or is no longer in effect.
    c. **ARTG** means the Australian Register of Therapeutic Goods maintained under section 9A of the *Therapeutic Goods Act 1989*.
    d. **CAPs** means, as applicable:
        i. the conformity assessment procedures, as defined in section 41DA of the Act; or
        ii. requirements comparable to those procedures, within the meaning of sections 41BIA and 41BIB of the Act.
    e. **Complaint Information** means any information (other than Adverse Event Information) that the Sponsor is aware of relating to:
        i. any malfunction or deterioration in the characteristics or performance of the kind of device;
        ii. any inadequacy in the design, manufacture, labelling, instructions for use 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 has led to any complaint or problem in relation to the kind of device, no matter how minor.

f. **COI** means a condition imposed on the inclusion of a kind of medical device in the ARTG under Division 2 of Part 4-5 of the Act.

g. **Device** means any kind of medical device included in the ARTG in relation to the Sponsor under any ARTG number particularised in Column 2 of Appendix A to this notice.

h. **Device Incident Report** or **DIR** means a report submitted to the MDIR System concerning a kind of device included in the ARTG in relation to the Sponsor.

i. **Essential Principles** means the requirements for medical devices referred to in section 41CA of the Act, and set out in Schedule 1 of the Medical Devices Regulations.

j. **Manufacturer** has the meaning in subsection 41BG(1) of the Act, namely the manufacturer of a medical device is the person who is responsible for the design, production, packaging and labelling of the device before it is supplied under the person's name, whether or not it is the person, or another person acting on the person's behalf, who carries out those operations.

k. the **MDIR System** is the TGA's Medical Device Incident Report system.

l. **Medical Devices Regulations** means the *Therapeutic Goods (Medical Devices) Regulations 2002*.

m. the **Secretary** means the Secretary of the Department of Health and Aged Care.

n. **Sponsor** means Medtronic Australasia Pty Ltd.

o. **TGA** means the Therapeutic Goods Administration.

Part C – Information you are required to give

6. The information which I require the Sponsor to give to the Secretary is:

   a. each model or kind of device included in the ARTG under each ARTG number particularised in Appendix A to this notice;

   b. in relation to each model or kind of device supplied in Australia under an ARTG number particularised in Appendix A to this notice:

      i. the current install base in Australia;

      ii. the total number of devices supplied in Australia on or after 1 Jan 2019;

      iii. for each year of supply:

         1. the number of devices supplied in that year;

         2. the number of times that Adverse Event Information was received by the Sponsor;

         3. the number of times that Complaint Information was received by the Sponsor;

c. for any Adverse Event Information which became known to the Sponsor on or after 1 Jan 2019 related to any Device:
    i. the Sponsor's or Manufacturer's complaint or adverse event reference number (or similar);
    ii. if the Adverse Event Information was reported to the TGA through the MDIR System, the DIR number and date of report;
    iii. if the Adverse Event Information relates to an event or other occurrence, the date of that event or other occurrence;
    iv. the person or persons that notified the Sponsor of the Adverse Event Information;
    v. the date of that the Sponsor became aware of the Adverse Event Information;
    vi. a summary of the Adverse Event Information, including (if applicable) a summary of the event or other occurrence to which the Adverse Event Information relates;
    vii. if (and, if so, the date that) the Sponsor notified the Manufacturer of the Adverse Event Information;
    viii. the date or dates that the Sponsor reviewed the Adverse Event Information and decided whether to report the information to the TGA through the MDIR System, and any contemporaneous explanation for why the Adverse Event Information was or was not provided to the TGA through the MDIR System.
d. for any Complaint Information which became known to the Sponsor on or after 1 Jan 2019 related to any Device:
    i. the Sponsor's or Manufacturer's complaint or adverse event reference number (or similar);
    ii. if the Complaint Information was reported to the TGA through the MDIR System, the DIR number and date of report
    iii. if the Complaint Information relates to an event or other occurrence, the date of that event or other occurrence;
    iv. the person or persons that notified the Sponsor of the Complaint Information;
    v. the date of that the Sponsor became aware of the Complaint Information;
    vi. a summary of the Complaint Information, including (if applicable) a summary of the event or other occurrence to which the Complaint Information relates;
    vii. if (and, if so, the date that) the Sponsor notified the Manufacturer of the Complaint Information;
    viii. the date or dates that the Sponsor reviewed the Complaint Information and decided whether to report the information to the TGA through the MDIR System, and any contemporaneous explanation for why the Complaint Information was or was not provided to the TGA through the MDIR System.

Part D – Documents you are required to produce

7. The documents which I require the Sponsor to produce to the Secretary are:
    a. any documents evidencing the Sponsor's current policies or procedures concerning the Sponsor's processes in relation to one or more of the following:
        i. seeking, collecting, receiving, reviewing, trending, analysing, investigating or reporting Adverse Event Information or Complaint Information;
        ii. if or when information (including Adverse Event Information or Complaint Information) concerning any kind of medical device should be reported to the TGA;
        iii. post-market monitoring of the Devices;
        iv. providing Adverse Event Information or Complaint Information to the Manufacturer.
    b. In relation to each Adverse Event Information identified by the Sponsor in response to paragraph 6.c. of this notice, a copy of the document or documents from which the Sponsor has identified:
        i. the date that the Sponsor became aware of the Adverse Event Information;
        ii. the person or persons that notified the Sponsor of the Adverse Event Information; and
        iii. the method by which the person or persons notified the Sponsor of the Adverse Event Information.
    c. In relation to each Complaint Information identified by the Sponsor in response to paragraph 6.d. of this notice, a copy of the document or documents from which the Sponsor has identified:
        i. the date that the Sponsor became aware of the Complaint Information;
        ii. the person or persons that notified the Sponsor of the Complaint Information; and
        iii. the method by which the person or persons notified the Sponsor of the Complaint Information.

Part E – Manner in which information and documents must be provided

2. The information in Part C must be given to the Secretary in a table in the same (or a materially similar) format to:
    a. Appendix B to this notice, in relation to the information particularised in items 6.a and 6.b above;
    b. Appendix C to this notice, in relation to the information particularised in items 6.c and 6.d above.

    Each table must be provided in a text-editable Word or Excel document.
3. All information provided in response to Part C must be provided in English. Where a document responsive to an item in Part D is not in English, a copy of the document and a certified translation must be provided.

4. All text and pictures must be legible, and pictures must be clearly labelled. The electronic information must be complete, and clearly tabulated and titled.
5. Excel spreadsheets (and any other data file) must be produced in native format. Other kinds of documents may be produced in native format or converted to pdf.
6. Submissions less than 15MB can be emailed to IRIS@health.gov.au, clearly stating the Sponsor and our reference number in the subject line.
7. For submissions greater than 15MB, the information can be provided as an electronic copy via GovTEAMS (www.govteams.gov.au) and citing our reference number. If you wish to proceed, send an email to devices@tga.gov.au, and GovTEAMS registration will be arranged.
8. While not a requirement, I invite you to provide a cover letter to your response which:
    a. summarises and itemises the relevant attachments and information that relates to each item in Parts C and D;
    b. provides submissions concerning any potential deficiency in the Sponsor's or the Manufacturer's processes (or anything else that may be relevant to the TGA's considerations of compliance with adverse event reporting requirements and related matters).

Part F – Information about this notice

9. Failure to comply with this notice is a criminal offence under section 45AC of the Act. A contravention of section 45AC is punishable by a fine of up to 500 penalty units for an individual or 2,500 penalty units for a body corporate.[6] Copies of the legislative provisions relevant to this notice are at Appendix D.
10. Providing information or documents that are false or misleading in a material particular in response to this notice is a criminal offence under section 45AD of the Act. A contravention of section 45AD of the Act by an individual is punishable by a sentence of imprisonment of up to 12 months or a fine of up to 1,000 penalty units, or both. A contravention by a body corporate is punishable by a fine of up to 5,000 penalty units.
11. Giving false or misleading information or documents in compliance or purported compliance with a law of the Commonwealth is also a serious criminal offence under sections 137.1 and 137.2 of the Criminal Code (Cth).

Yours sincerely

Signed electronically by

s22 [redacted]
Delegate of the Secretary
Medical Devices Surveillance Branch
Therapeutic Goods Administration
8 May 2024

[6] The value of a penalty unit is currently $313 (Crimes Act 1914, subsection 4AA(1)).

Appendix A

List of ARTG entries

ARTG number	Manufacturer name	GMDN code	GMDN text descriptor
392267	Medtronic Inc	64970	Analgesic spinal cord electrical stimulation system pulse generator implantable
389797	Medtronic Inc	64970	Analgesic spinal cord electrical stimulation system pulse generator implantable
389798	Medtronic Inc	64970	Analgesic spinal cord electrical stimulation system pulse generator implantable
386867	Medtronic Inc	64970	Analgesic spinal cord electrical stimulation system pulse generator implantable
386887	Medtronic Inc	64970	Analgesic spinal cord electrical stimulation system pulse generator implantable
298746	Medtronic Inc	36007	Stimulator, electrical, analgesic, spinal cord
293256	Medtronic Inc	36007	Stimulator, electrical, analgesic, spinal cord
280179	Medtronic Inc	36007	Stimulator, electrical, analgesic, spinal cord

280180	Medtronic Inc	36007	Stimulator, electrical, analgesic, spinal cord
215751	Medtronic Inc	36007	Stimulator, electrical, analgesic, spinal cord

Appendix B

Details of models / kind of devices and supply information

ARTG number	Model or kind of device (separate row for each model or kind)	Current install base	Total number of devices supplied in Australia on or after 1 Jan 2019	Supply year from when records are available	Number of devices suppled in year	Number of times that Adverse Event Information was received in the year	Number of times that Complaint Information was received in the year
				e.g. 2019			
				2020			
				2021			
				2022			
				2023			
				2024			

Appendix C

Details of Complaint Information or Adverse Event Information

Please provide one tables for Complaint Information, and another table for Adverse Event Information

ARTG number	Model / kind of device	Complaint / Adverse event reference number (according to sponsor/ manufacturer)	If applicable, the TGA DIR number and date of reporting	If applicable, date of event or occurrence	Source of complaint/ adverse event	Date you become aware of complaint / adverse event	Summary of adverse event / complaint	Date you notified manufacturer of complaint / adverse event, if any	Date(s) you reviewed the complaint / adverse event and decided whether to report to the TGA	Any contemporaneous explanation for why the adverse event / complaint was or was not reported to the TGA

Appendix D

Legislation references

Therapeutic Goods Act 1989

Division 2—Obtaining information or documents

45AB Secretary may require information or documents

(1) The Secretary may, by written notice given to a person, require the person to give to the Secretary any information, or produce to the Secretary any documents, specified in the notice that are relevant to a contravention, or possible contravention, of a provision of this Act or the regulations.

(2) The notice must specify a reasonable period within which the person must comply with the notice. The period must be at least 14 days starting on the day on which the notice is given.

(3) The notice must set out the effect of the following:
  (a) section 45AC (about failure to comply with notice);
  (b) section 45AD (about giving false or misleading information or documents);
  (c) section 137.1 of the *Criminal Code* (about giving false or misleading information);
  (d) section 137.2 of the *Criminal Code* (about producing false or misleading documents).

(4) The notice may require the information to be given, or the documents to be produced, in accordance with specified software requirements:
  (a) on a specified kind of data processing device; or
  (b) by way of a specified kind of electronic transmission.

45AC Offences for failing to comply with notice

Fault-based offence

(1) A person commits an offence if:
  (a) the person is given a notice under section 45AB; and
  (b) the person fails to comply with the notice.

Penalty: 500 penalty units.

Strict liability offence

(2) A person commits an offence of strict liability if:
  (a) the person is given a notice under section 45AB; and
  (b) the person fails to comply with the notice.

Penalty: 100 penalty units.

Exception

(3) Subsection (1) or (2) does not apply if the person has a reasonable excuse.

Note: A defendant bears an evidential burden in relation to the matter in subsection (3): see subsection 13.3(3) of the *Criminal Code*.

45AD Offences and civil penalty for giving false or misleading information or documents

Fault-based offence

(1) A person commits an offence if:
  (a) the person is given a notice under section 45AB; and
  (b) the person gives information, or produces a document, in compliance or purported compliance with the notice; and
  (c) the information or document is false or misleading in a material particular.

Note: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

Strict liability offence

(2) A person commits an offence of strict liability if:
  (a) the person is given a notice under section 45AB; and
  (b) the person gives information, or produces a document, in compliance or purported compliance with the notice; and
  (c) the information or document is false or misleading in a material particular.

Penalty: 100 penalty units.

Civil penalty provision

(3) A person contravenes this subsection if:
  (a) the person is given a notice under section 45AB; and
  (b) the person gives information, or produces a document, in compliance or purported compliance with the notice; and
  (c) the information or document is false or misleading in a material particular.

Maximum civil penalty:
  (a) for an individual—5,000 penalty units; and
  (b) for a body corporate—50,000 penalty units.

45AE Self-incrimination

(1) An individual is not excused from giving information or producing a document under section 45AB on the ground that giving the information or producing the document might tend to incriminate the individual in relation to an offence.

Note: A body corporate is not entitled to claim the privilege against self-incrimination.

(2) However:
  (a) the information given or document produced; and
  (b) the giving of the information or the production of the document; and
  (c) any information, document or thing obtained as a direct or indirect consequence of the giving of the information or the production of the document;

are not admissible in evidence against the individual in criminal proceedings other than proceedings for an offence against:
  (d) subsection 45AC(1) or (2); or
  (e) subsection 45AD(1) or (2); or
  (f) section 137.1 or 137.2 of the *Criminal Code* in relation to giving the information or producing the document.

(3) If, at general law, an individual would otherwise be able to claim the privilege against self-exposure to a penalty (other than a penalty for an offence) in relation to giving information or producing a document under section 45AB, the individual is not excused from giving the information or producing the document under that provision on that ground.

Note: A body corporate is not entitled to claim the privilege against self-exposure to a penalty.

41FN Conditions applying automatically

Availability etc. of information

(3) The inclusion of a kind of medical device in the Register is subject to conditions that:
  (a) at all times while the inclusion in the Register has effect, the person in relation to whom the kind of device is included in the Register:

(i) has available sufficient information to substantiate compliance with the essential principles; or

(ii) has procedures in place, including a written agreement with the manufacturer of the kind of device, to ensure that such information can be obtained from the manufacturer within 20 working days; and

(b) at all times while the inclusion in the Register has effect, the person in relation to whom the kind of device is included in the Register:

(i) has available sufficient information to substantiate that the conformity assessment procedures have been applied to the kind of medical device or that requirements, comparable to those procedures, have been applied to the kind of medical device to the satisfaction of an overseas regulator; or

(ii) has procedures in place, including a written agreement with the manufacturer of the kind of device, to ensure that such information can be obtained from the manufacturer within 20 working days; and

(ba) at all times while the inclusion in the Register has effect, the person in relation to whom the kind of device is included in the Register:

(i) has available information relating to changes to the kind of medical device, the product range or quality management system by the manufacturer of the kind of device; or

(ii) has procedures in place, including a written agreement with the manufacturer of the kind of device, to ensure that such information can be obtained from the manufacturer within 20 working days; and

(c) at any time while the inclusion in the Register has effect, the person in relation to whom the kind of device is included in the Register will, if asked to do so by the Secretary, give the information to the Secretary; and

(d) the person in relation to whom the kind of device is included in the Register will give information of a kind mentioned in subsection 41MP(2) or 41MPA(2) to the Secretary within the period specified in the regulations; and

(e) the person in relation to whom the kind of device is included in the Register will give the manufacturer of the kind of medical device information relevant to:

(i) the manufacturer's obligations under the conformity assessment procedures or requirements comparable to those procedures; and

(ii) whether medical devices of that kind comply with the essential principles.

(4) The regulations may prescribe the amount, standard or kind of information or evidence required for the purposes of paragraphs (3)(c), (d) and (e).

41MPA Civil penalty for failing to notify adverse events etc.

(1) A person contravenes this section if:

(a) a kind of medical device is included in the Register in relation to the person; and

(b) the information is of a kind mentioned in subsection (2); and

(c) the person does not give information of a kind mentioned in subsection (2) to the Secretary within the period specified in the regulations (whether or not the person has already given to the Secretary other information relating to the same matter).

Maximum civil penalty:

(a) for an individual—3,000 penalty units; and

(b) for a body corporate—30,000 penalty units.

(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, instructions for use 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 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:

(i) compliance with the essential principles; or

(ii) 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;

has been restricted, suspended, revoked or is no longer in effect.

41MNA Civil penalties for breaching conditions

(1) A person contravenes this subsection if:

(a) a kind of medical device is included in the Register in relation to the person; and

(b) the person does an act or omits to do an act; and

(c) the act or omission breaches a condition of the inclusion of the kind of device in the Register.

Maximum civil penalty:

(a) for an individual—5,000 penalty units; and

(b) for a body corporate—50,000 penalty units.

Therapeutic Goods (Medical Devices) Regulations 2002

5.7 Conditions applying automatically—period for giving information about adverse events etc (Act s 41FN)

(1) For paragraph 41FN(3)(d) of the Act, the period in which a person in relation to whom a kind of medical device is included in the Register must give information of a kind mentioned in subsection 41MP(2) or 41MPA(2) of the Act to the Secretary is:

(a) if the information relates to an event or other occurrence that represents a serious threat to public health—48 hours after the person becomes aware of the event or occurrence; and

(b) if the information relates to an event or other occurrence that led to the death, or a serious deterioration in the state of health, of a patient, a user of the device, or another person—10 days after the person becomes aware of the event or occurrence; and

(c) if the information relates to an event or other occurrence a recurrence of which might lead to the death, or a serious deterioration in the state of health, of a patient, a user of the device, or another person—30 days after the person becomes aware of the event or occurrence; and

(d) in any other case—60 days after the person becomes aware of the information.

Note: See also regulation 5.8A (which deals with the giving of a report after information is given within a period covered by paragraph (1)(a), (b) or (c) of this regulation).

(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.

(3) For paragraphs (1)(b) and (c), an event or other occurrence leads to a ***serious deterioration*** in the state of health of a person if the event or other occurrence causes, or contributes to:

(a) a life-threatening illness or injury suffered by the person; or

(b) a permanent impairment of a bodily function of the person; or

(c) permanent damage to a body structure of the person; or

(d) a condition requiring medical or surgical intervention to prevent such permanent impairment or damage.

5.8 Conditions applying automatically—requirements in relation to information about kind of medical device (Act s 41FN)

For subsection 41FN(4) of the Act, the information required for the purposes of paragraph 41FN(3)(e) of the Act in relation to a kind of medical device that is included in the Register in relation to a person is:

(a) any information that the person is aware of relating to:

(i) any malfunction or deterioration in the characteristics or performance of the kind of device; or

(ii) any inadequacy in the design, manufacture, labelling, instructions for use 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 has led to any complaint or problem in relation to the kind of device, no matter how minor; and

(b) any information of the kind mentioned in subsection 41MP(2) of the Act that the person is aware of in relation to the kind of device.

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Our Reference: E24-30346

Sent by email

Dear s22

Subject: Medical Devices Vigilance Program - Inspection of Medtronic Australasia Pty Ltd located at 2 Alma Road, MACQUARIE PARK NSW 2113

I would like to thank you and your staff for the courtesy and attention extended during the *TGA Medical Devices Vigilance Program - Pilot* inspection that took place at your Australian sponsor facility on 30 October 2024.

During the inspection, observations regarding regulatory compliance were discussed with you and your representatives. These are included in the following Medical Devices Vigilance Program Inspection Report. No non-compliances have been raised and hence no action is required in response to this report.

All correspondence regarding the inspection should be addressed to me at the email address below.

Yours sincerely
Signed electronically by

s22
Senior MDVP Inspector
Medical Devices Vigilance Program
Devices Vigilance and Policy Section
Medical Devices Surveillance Branch
Therapeutic Goods Administration

26 February 2025

Phone: s22; Mobile: s22;

Email: mdvp@health.gov.au

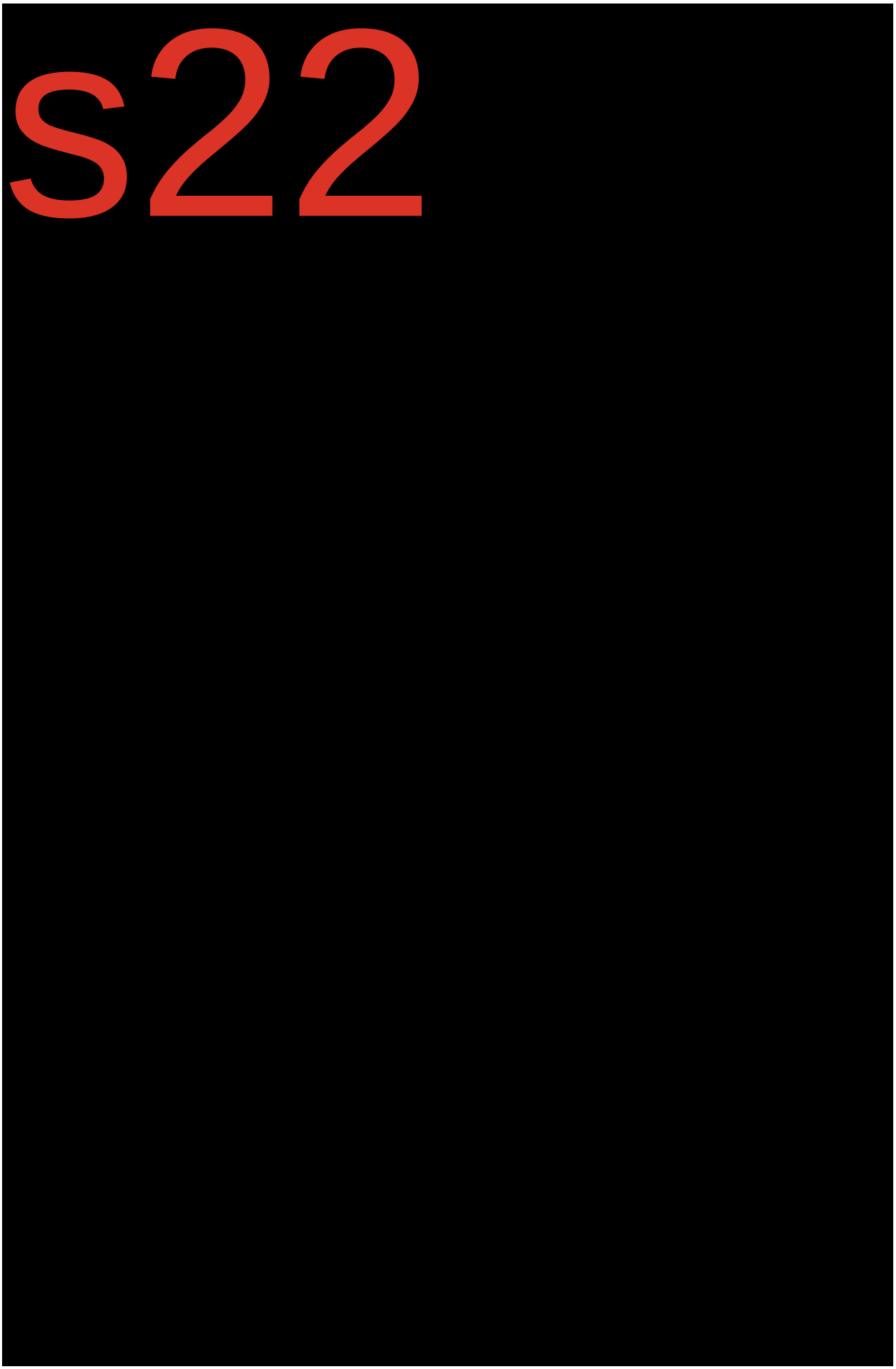
Location: Sydney, Australia

MEDICAL DEVICES VIGILANCE PROGRAM
INSPECTION REPORT

Sponsor name	Medtronic Australasia Pty Ltd (837)
Inspection site	2 Alma Road, MACQUARIE PARK NSW 2113
Inspection objective	To conduct an on-site inspection under the *Medical Devices Vigilance Program – Pilot*
Inspection criteria	• *Therapeutic Goods Act 1989* (s41FN, s41MP(2)/MPA(2), s41KA) • *Therapeutic Goods (Medical Devices) Regulations 2002* (5.7. 5.8, 5.8A, 5.10, 5.11)
Inspection scope	Conditions of inclusion in the ARTG: s22 [redacted] • Adverse Events Reporting (inc. complaints/problems) s22 [redacted] s22 [redacted]
Inspection type	Pilot
Sponsor ARTG portfolio	Approx. 1650 active medical device entries related to neuroscience, medical surgery, cardiovascular and diabetes specialities, consisting of class AIMD (1), III** (~560), IIb* (implantable ~70 / non-implantable ~215), IIa* (~330), Is (~95), Im (~15) and I* (~350), including class 1 (2), 2 (3) IVDs
Inspection date(s)	30 October 2024
Inspector(s)	• s22 [redacted] – Lead Inspector • s22 [redacted] – Inspector-in-training
References ***(for TGA internal use)***	s22 [redacted]

Executive Summary

s22 [redacted]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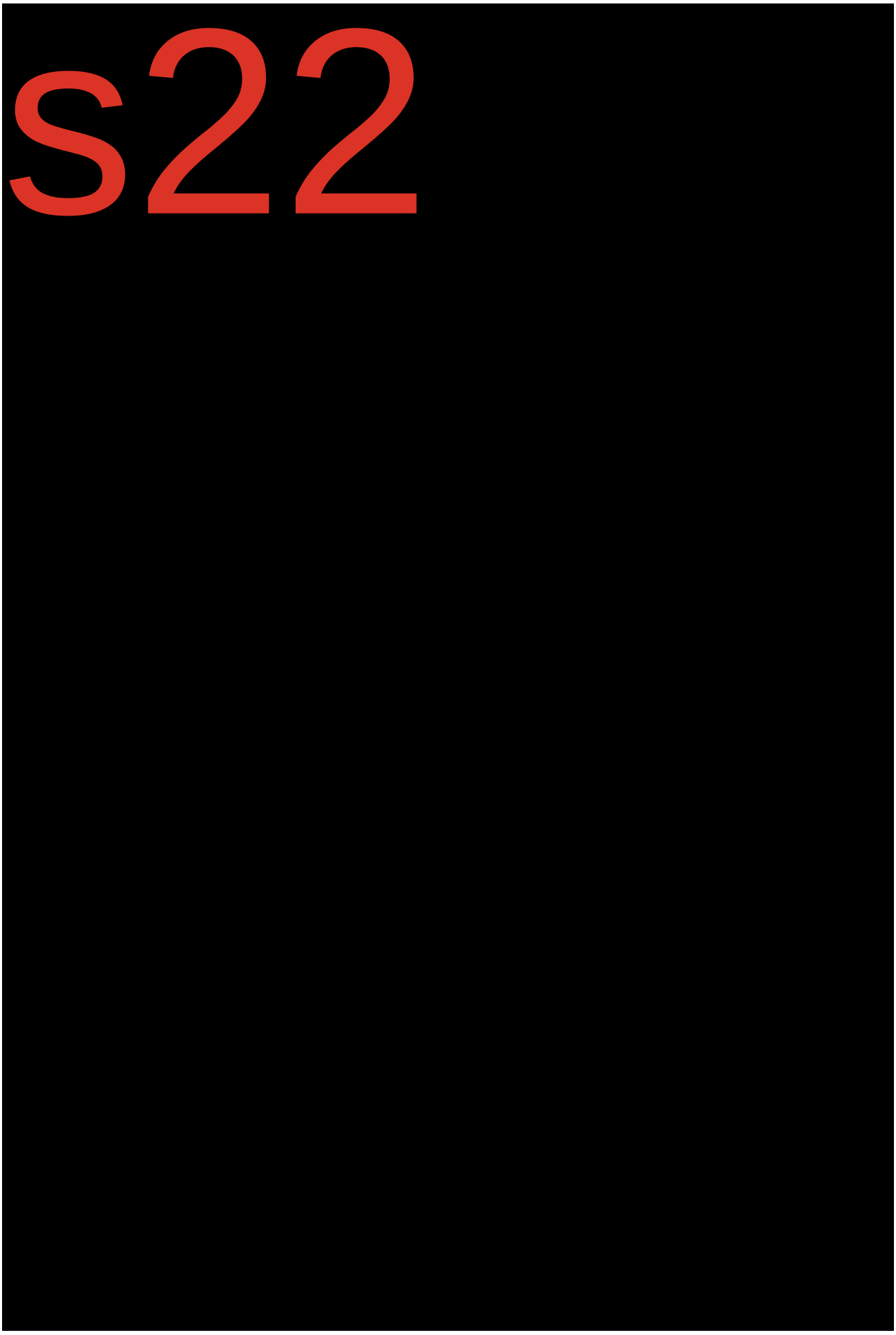
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Reporting Adverse Events (including complaints and problems)

The sponsor had processes and documented procedures in place for handling complaints or device problems 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 their state of health (i.e. an adverse event).

The procedures included steps for recording complaints (product events) into the Global Complaint Handling (GCH) system and obtaining additional information (consulting with user/clinician/healthcare professional and requesting device/sample) for investigation and decision-making, e.g. root cause analysis of complaint/problem, making adverse event determination.

The sponsor had a documented procedure in place for reporting adverse events to the TGA, including provision of a written report within 120 days. The procedure included criteria for adverse event determination and meeting the specified timeframes.

Records of complaints, adverse event determinations (including rationale for decisions) and adverse events were maintained. Records as evidence of reporting compliance were reviewed and deemed to generally comply with the reporting requirements.

Written adverse event reports were maintained and forwarded by the sponsor to the TGA within the specified 120 days' timeframe.

Over the past 2 years, approximately 800-1000 adverse events have been reported to the TGA (~30-40/month).

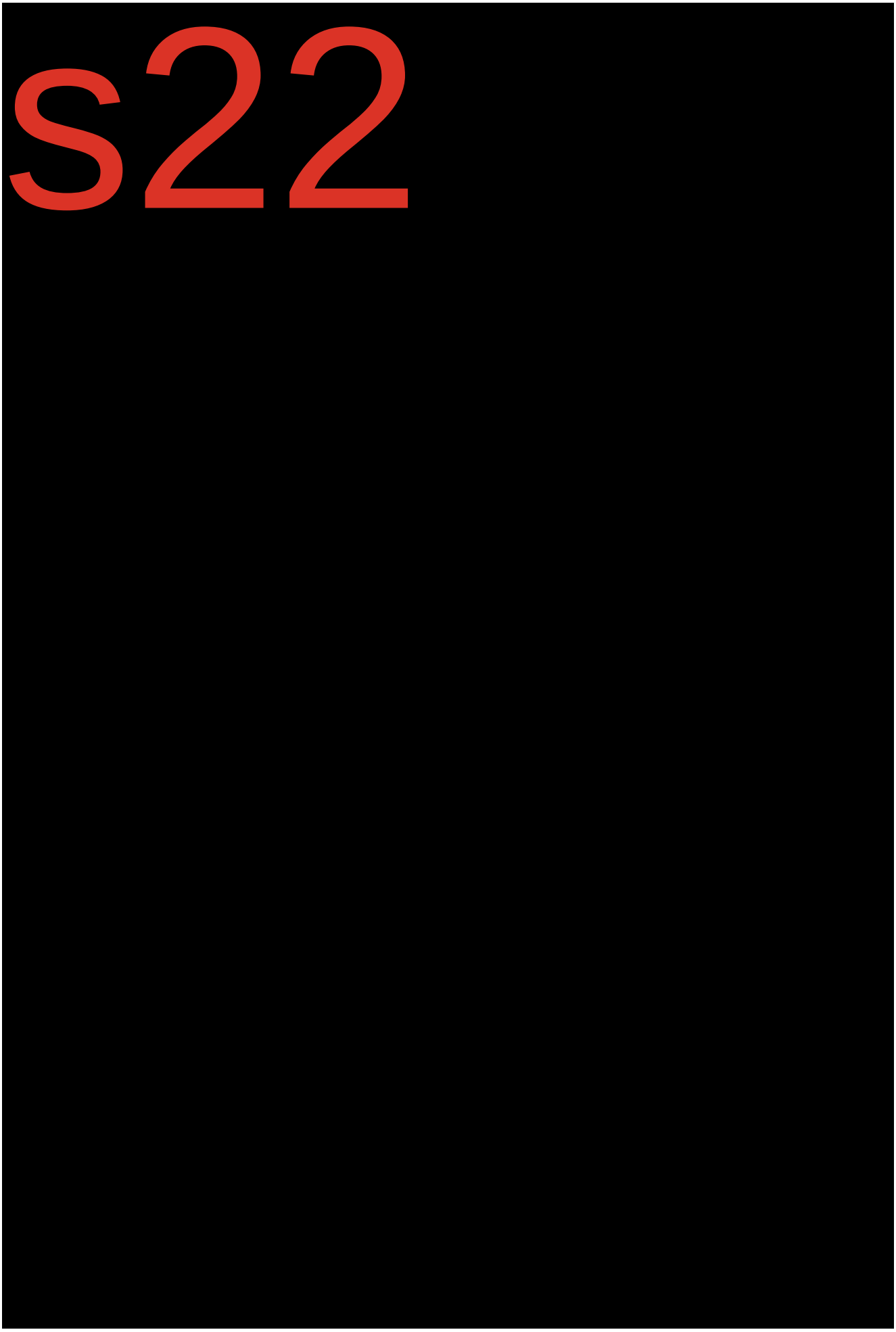
TGA records indicated that the sponsor was the source of reporting for 77% of medical device adverse events notified to the TGA that related to *Medtronic* products in Australia. Adverse events were also reported to the TGA directly by nurses, medical specialists and hospital administration personnel.

Issues previously raised by the TGA's post-market review and monitoring processes were followed up at the inspection:

- Post-Market Review of complaints and reportability decisions related to *spinal cord stimulator* ARTG listings.

  At the inspection, review of a sample of complaint records related to spinal cord stimulators did not indicate that the complaints met the criteria for reporting as adverse events to the TGA, regardless of the use of 'exemption rules' for adverse event determination.

s22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List of key documents and records reviewed

For a full list of documents and records reviewed, refer to the Inspector's notes.

List Identifier	List Title
s22	
PE 706124650 PE 706124833 PE 706124879 PE 706131235 PE 706135003 PE 706136483 PE 706136626 PE 706140847 PE 706143515 PE 706147757	Complaints – sample of spinal cord stimulators; examples from 2023-2024

DIR 97911	*Medtronic Inc*. analgesic spinal cord electrical stimulation system, pulse generator, implantable - led to seizure; 30/5/24

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Related to DIR 97911	Medtronic Pain Therapy – Intellis™, Vanta™, Sequentia™ LT neurostimulation systems for pain therapy (Information for prescribers), 31/1/22
PE 0704140233 PR522036 Related to DIR 97911	Nonconformance Detail Report, 28/5/21 (similar incident to DIR 97911, dated 30/5/24)
Related to DIR 97911	TGA Closure Confirmation - ARTG 392267, 2/8/24

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