



Therapeutic Goods Legislation Amendment (Australian Unique Device Identification Database and Other Measures) Regulations 2025

I, the Honourable Sam Mostyn AC, Governor-General of the Commonwealth of Australia, acting with the advice of the Federal Executive Council, make the following regulations.

Dated 20 March 2025

Sam Mostyn AC
Governor-General

By Her Excellency's Command

Mark Butler
Minister for Health and Aged Care

Contents

1	Name	1
2	Commencement.....	1
3	Authority	1
4	Schedules.....	1
Schedule 1—Australian Unique Device Identification Database		2
Part 1—Main amendments		2
<i>Therapeutic Goods (Medical Devices) Regulations 2002</i>		2
Part 2—Application provisions		12
<i>Therapeutic Goods (Medical Devices) Regulations 2002</i>		12
Schedule 2—Mandatory reporting of adverse events involving medical devices		13
Part 1—Stage 1 amendments		13
<i>Therapeutic Goods (Medical Devices) Regulations 2002</i>		13
Part 2—Stage 2 amendments		15
<i>Therapeutic Goods (Medical Devices) Regulations 2002</i>		15
Schedule 3—Refund of fees		16
<i>Therapeutic Goods Regulations 1990</i>		16

1 Name

This instrument is the *Therapeutic Goods Legislation Amendment (Australian Unique Device Identification Database and Other Measures) Regulations 2025*.

2 Commencement

- (1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	Column 2	Column 3
Provisions	Commencement	Date/Details
1. Sections 1 to 4 and anything in this instrument not elsewhere covered by this table	The day after this instrument is registered.	25 March 2025
2. Schedule 1	The day after this instrument is registered.	25 March 2025
3. Schedule 2, Part 1	21 March 2026.	21 March 2026
4. Schedule 2, Part 2	1 April 2028.	1 April 2028
5. Schedule 3	The day after this instrument is registered.	25 March 2025

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

- (2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under the *Therapeutic Goods Act 1989*.

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Australian Unique Device Identification Database

Part 1—Main amendments

Therapeutic Goods (Medical Devices) Regulations 2002

1 After Part 9

Insert:

Part 9A—Australian Unique Device Identification Database

9A.1 Australian Unique Device Identification Database

- (1) For the purposes of section 41CE of the Act, the following provisions of this regulation have effect.

Establishing the database

- (2) The Secretary must cause a database to be established (the *Australian Unique Device Identification Database*).

Maintaining the database

- (3) The Secretary must:
- (a) maintain the whole of the database; or
 - (b) on behalf of the Commonwealth, enter into a written agreement with a person to maintain the whole of the database; or
 - (c) maintain some of the content of the database and, on behalf of the Commonwealth, enter into a written agreement with a person to maintain the remaining content of the database.

Personal information

- (4) The database must not include personal information, unless the personal information:
- (a) is the name of a person in relation to whom a kind of medical device is included in the Register; or
 - (b) is about an authorised representative of the manufacturer of a kind of medical device; or
 - (c) is about an authorised representative of a person in relation to whom a kind of medical device is included in the Register.
- (5) Personal information covered by paragraph (4)(b) or (c) must not be included in the database unless the authorised representative concerned consents, in writing, to that inclusion.

Retention of information during suspension or cancellation of Register entry

- (6) If information is included in the database in relation to UDI medical devices that are a type of model and that model is covered by a suspension under Part 4-6 of the Act, that information must not be removed from the database during the period of the suspension unless the Secretary is satisfied that it is appropriate in all the circumstances to do so.
- (7) If information is included in the database in relation to UDI medical devices that are a type of model and that model is covered by a cancellation under Part 4-6 of the Act, that information must not be removed from the database unless the Secretary is satisfied that it is appropriate in all the circumstances to do so.

Removal of information

- (8) The Secretary may remove information from the database in relation to UDI medical devices that are a type of model if:
 - (a) the information is not information required by this instrument to be included in the database; and
 - (b) a sponsor or manufacturer of those medical devices requests the Secretary, in writing, to remove the information.
- (9) The Secretary may remove information from the database in relation to UDI medical devices that are a type of model if the Secretary is satisfied that the information is incomplete or incorrect.
- (10) The Secretary must remove information from the database that is personal information, other than personal information covered by paragraph (4)(a), (b) or (c).
- (11) However, the Secretary must remove personal information covered by paragraph (4)(b) or (c) from the database if the authorised representative concerned requests the Secretary, in writing, to do so.

Corrections to information

- (12) The Secretary may correct information in the database in relation to UDI medical devices that are a type of model if the Secretary is satisfied that:
 - (a) it is not possible or practicable for a sponsor or manufacturer, or another person on behalf of a sponsor or manufacturer, of those medical devices to make the correction; or
 - (b) it is in the interests of public health or safety to do so.

Making database publicly available

- (13) The Secretary may arrange for the whole or a part of the database to be made publicly available. However, personal information covered by paragraph 41CE(2)(b) or (c) of the Act must not be made publicly available.

2 Subregulation 10.7(1) (at the end of the definition of *initial decision*) (before the note)

Add:

; (e) subregulation 9A.1(9).

3 Part 2 of Schedule 1 (heading)

Repeal the heading, substitute:

Part 2—Other principles

4 After clause 13.4 of Schedule 1

Insert:

13.5 UDI medical devices—UDI device identifier and UDI production identifier

- (1) For a UDI medical device, the UDI device identifier, and the UDI production identifier, of the UDI medical device must be provided with the UDI medical device in accordance with this clause.

General rule

- (2) Subject to this clause:
- (a) subject to paragraphs (b) and (c), each identifier, in human-readable form and machine-readable form, must be provided on the UDI medical device itself; or
 - (b) subject to paragraph (c), if it is impracticable or inappropriate to comply with paragraph (a), each identifier, in human-readable form and machine-readable form:
 - (i) must be provided on the packaging used for the UDI medical device, unless subparagraph (ii) applies; or
 - (ii) if the UDI medical device is packaged together with other such UDI medical devices because individual packaging of the UDI medical devices for supply is not practicable—must be provided on the outer packaging used for the UDI medical devices; or
 - (c) if it is impracticable or inappropriate to comply with paragraphs (a) and (b)—each identifier, in human-readable form and machine-readable form:
 - (i) if the UDI medical device is not software—must be provided on a leaflet supplied with the UDI medical device; or
 - (ii) if the UDI medical device is software—must be provided on a leaflet supplied with the UDI medical device or must be provided electronically.

UDI medical device to which clause 13C.5 applies

- (3) For a UDI medical device to which clause 13C.5 applies, on and after the direct marking start day for the UDI medical device, subclause (2) of this clause ceases to apply in relation to the UDI medical device. Instead:
- (a) subject to paragraph (b), each identifier, in human-readable form and machine-readable form:
 - (i) must be provided on the packaging used for the UDI medical device, unless subparagraph (ii) applies; or
 - (ii) if the UDI medical device is packaged together with other such UDI medical devices because individual packaging of the UDI medical devices for supply is not practicable—must be provided on the outer packaging used for the UDI medical devices; or

- (b) if it is impracticable or inappropriate to comply with paragraph (a)—each identifier, in human-readable form and machine-readable form, must be provided on a leaflet supplied with the UDI medical device.

Qualification for UDI medical device intended by manufacturer to be supplied at retail premises

- (4) For a UDI medical device that is intended by the manufacturer to be supplied at retail premises, the UDI production identifier of the UDI medical device, in machine-readable form, is not required to be provided with the UDI medical device.

13.6 UDI medical devices—medical device packaging identifier

- (1) If a type of packaging is used for a UDI medical device, the medical device packaging identifier of that packaging must be provided with the UDI medical device.
- (2) That identifier, in human-readable form and machine-readable form, must be provided on the packaging of the UDI medical device.

5 Paragraphs 13A.2(1)(a) and (b) of Schedule 1

Repeal the paragraphs, substitute:

- (a) a card (a *patient implant card*) that:
 - (i) in any case—includes the information covered by subclause (2) and that satisfies clause 13A.4; and
 - (ii) for a UDI medical device—includes the UDI device identifier, and the UDI production identifier, of the UDI medical device (where each identifier is in human-readable form and machine-readable form); must be made available for provision to the patient concerned; or
- (b) the following:
 - (i) in any case—information covered by subclause (2) and that satisfies clause 13A.4;
 - (ii) for a UDI medical device—the UDI device identifier, and the UDI production identifier, of the UDI medical device (where each identifier is in human-readable form and machine-readable form); must be made available electronically and in a way that is readily accessible by the patient concerned.

6 After clause 13B of Schedule 1

Insert:

13C Rules for UDI medical devices

13C.1 Identifiers relating to UDI medical devices

- (1) For UDI medical devices that are a type of model, the UDI device identifier of those medical devices must have been issued by a UDI issuing agency.
- (2) For UDI medical devices that are a type of model, the UDI production identifier of those medical devices must have been allocated by, or on behalf of, the

manufacturer in accordance with any applicable requirements of the UDI issuing agency that issued the UDI device identifier of those medical devices.

- (3) If a type of packaging is used for UDI medical devices that are a type of model, the medical device packaging identifier of that packaging must have been issued by a UDI issuing agency.
- (4) In relation to UDI medical devices that are a type of model, the identifiers covered by subclauses (1) and (3) must have been issued by the same UDI issuing agency.

13C.2 Inclusion of identifiers in the Australian Unique Device Identification Database

Inclusion of UDI device identifiers

- (1) For UDI medical devices that are a type of model:
 - (a) the UDI device identifier of those medical devices must be included in the Australian Unique Device Identification Database; and
 - (b) the name of the UDI issuing agency that issued the UDI device identifier must be included in that database.

Note: Subclause (5) deals with the circumstances in which there is a different type of model of UDI medical devices. The UDI device identifier of the UDI medical devices of the different type of model would then need to be included in that database.

Inclusion of medical device package identifiers

- (2) If a type of packaging is used for UDI medical devices that are a type of model, the medical device packaging identifier of that packaging must be included in the Australian Unique Device Identification Database.

Timing of inclusion of information

- (3) The information covered by subclause (1), for UDI medical devices that are a type of model, must be included in the Australian Unique Device Identification Database before the end of the period of 30 days beginning on the first day, that is on or after the general start day for the UDI medical devices, on which the UDI medical devices are supplied for use in Australia.
- (4) The information covered by subclause (2), for a type of packaging that is used for UDI medical devices that are a type of model, must be included in the Australian Unique Device Identification Database before the end of the period of 30 days beginning on the first day, that is on or after the general start day for the UDI medical devices, on which the UDI medical devices are supplied for use in Australia with that type of packaging.

Different models of medical devices

- (5) Subject to subclause (6), if a change (a **relevant change**) of the following kind occurs to or in relation to UDI medical devices that are a type of model, those medical devices, as affected by that change, are taken to be a different type of model:
 - (a) if the medical devices are not labelled as being for a single use only—the medical devices are labelled as being for a single use only;

- (b) the labels for the medical devices, or information provided with the medical devices, state that the medical devices contain latex;
- (c) a change to the magnetic resonance imaging safety status of the medical devices;
- (d) the labels for the medical devices, or information provided with the medical devices, state that the medical devices are packaged in a sterile state;
- (e) the labels for the medical devices, or information provided with the medical devices, state that the medical devices must be sterilised before use;
- (f) a change to the clinical size of the medical devices;
- (g) if the labels for the medical devices, or information provided with the medical devices, refer to a recommended number of reuses of the medical devices—a reduction in that recommended number of reuses;
- (h) a change to the brand name of the medical devices;
- (i) a change to the model number or version number of the medical devices;
- (j) a change to the quantity of the medical devices provided in a package;
- (k) if the medical devices are software—a change to the features of the software (including the addition of a new feature or a change to an existing feature) that results in a change to the safety, performance or intended purpose of the medical devices.

Note: The medical devices, before the change, remain a type of model.

- (6) If 2 or more relevant changes occur to or in relation to UDI medical devices that are a type of model as part of the same change in production of those medical devices, those medical devices, as affected by the 2 or more relevant changes, are taken to be a different type of model.
- (7) Subclause (5) does not limit the circumstances in which there may be a different type of model of UDI medical devices.

13C.3 Inclusion of other information in the Australian Unique Device Identification Database

- (1) For a UDI medical device, the following information must be included in the Australian Unique Device Identification Database:
 - (a) the identification number allocated to the manufacturer by the Therapeutic Goods Administration;
 - (b) the manufacturer's name or trading name;
 - (c) the brand name of the device;
 - (d) the device number in relation to the device;
 - (e) the model number or version number of the device;
 - (f) any additional identifiers that are associated with the device;
 - (g) any particular handling or storage requirements applying to the device;
 - (h) any warnings, restrictions, or precautions that should be taken, in relation to use of the device;
 - (i) any special operating instructions for the use of the device;
 - (j) the following:
 - (i) whether or not the device is intended for a single use only;

- (ii) if the device is not intended for a single use only—any restrictions on the number of times the device can be used;
- (k) if applicable, information about the method to sterilise the device;
- (l) whether or not a batch code, lot number or serial number is to be provided with the device;
- (m) whether or not the date of manufacture of the device, or the expiry date of the device, is to be provided with the device;
- (n) if the device is intended to be used in connection with blood, blood components or blood products—whether or not a donation identification number is able to be provided with the device;
- (o) whether or not the device is, or incorporates, software;
- (p) whether or not the device is a type of kit;
- (q) if the device is intended to be packaged together with UDI medical devices of the same model—the number of medical devices intended to be included in the base package.

Note: For the definition of *device number*, in relation to a medical device, see subsection 3(1) of the Act.

- (2) If the clinical size type of a UDI medical device is included in the Australian Unique Device Identification Database, then the clinical size value, and the clinical size unit of measure, of the UDI medical device must also be included in that database.
- (3) The information required to be included in that database by subclause (1) or (2) must be included in that database before the end of the period of 30 days beginning on the first day, that is on or after the general start day for the UDI medical device, on which the UDI medical device is supplied for use in Australia.

13C.4 Information in the Australian Unique Device Identification Database to be accurate and up to date

Information included in the Australian Unique Device Identification Database must be accurate and up to date.

13C.5 UDI device identifier and UDI production identifier to be directly marked on UDI medical device

- (1) For UDI medical devices that are a type of model and are intended by the manufacturer to be reprocessed between use on different patients, the UDI device identifier, and the UDI production identifier, of those medical devices:
 - (a) must be directly marked on those medical devices by the manufacturer; and
 - (b) must be directly marked as follows:
 - (i) in human-readable form and machine-readable form, unless subparagraph (ii) applies;
 - (ii) if it is impracticable or inappropriate for direct marking in both forms—in human-readable form or machine-readable form.
- (2) Subclause (1) does not apply in relation to UDI medical devices that are a type of model if:

- (a) those medical devices have been manufactured before the direct marking start day for those medical devices; or
- (b) those medical devices are implantable medical devices; or
- (c) the direct marking of the UDI device identifier, and the UDI production identifier, of those medical devices on those medical devices is likely to affect the safety, performance or effectiveness of those medical devices; or
- (d) it would be impracticable for the manufacturer to directly mark the UDI device identifier, and the UDI production identifier, of those medical devices on those medical devices.

7 Dictionary

Insert:

Australian Unique Device Identification Database: see regulation 9A.1.

direct marking start day, for a UDI medical device, means the following day:

- (a) for a Class I medical device that is supplied in a sterile state—1 July 2029;
- (b) for a Class IIa medical device—1 January 2029;
- (c) for a Class IIb medical device—1 January 2029;
- (d) for a Class III medical device—1 January 2028;
- (e) for a Class 1 IVD medical device with a Global Medical Device Nomenclature System Code of CT944 or CT943—1 July 2030;
- (f) for a Class 2 IVD medical device—1 July 2030;
- (g) for a Class 3 IVD medical device—1 July 2029;
- (h) for a Class 4 IVD medical device—1 July 2029.

EU certificate means an overseas regulator conformity assessment document issued under either of the following (as in force from time to time):

- (a) Council Directive 93/42/EEC of the Council of the European Communities;
- (b) Directive 98/79/EC of the European Parliament and the Council of the European Union.

general start day, for a UDI medical device, means the following day:

- (a) for a Class I medical device that is supplied in a sterile state:
 - (i) if, on 30 June 2028, an EU certificate is in force covering the medical device—1 January 2029; or
 - (ii) otherwise—1 July 2028;
- (b) for a Class IIa medical device:
 - (i) if, on 30 June 2027, an EU certificate is in force covering the medical device—1 January 2029; or
 - (ii) otherwise—1 July 2027;
- (c) for a Class IIb medical device that is an implantable medical device:
 - (i) if, on 30 June 2026, an EU certificate is in force covering the medical device and the medical device has been manufactured and labelled, but not supplied in Australia, before 1 January 2028—1 July 2029; or
 - (ii) if, on 30 June 2026, an EU certificate is in force covering the medical device and subparagraph (i) does not apply—1 January 2028; or

- (iii) if, on 30 June 2026, no EU certificate is in force covering the medical device and the medical device has been manufactured and labelled, but not supplied in Australia, before 1 July 2026—1 July 2029; or
- (iv) if, on 30 June 2026, no EU certificate is in force covering the medical device and subparagraph (iii) does not apply—1 July 2026;
- (d) for a Class IIb medical device that is not an implantable medical device:
 - (i) if, on 30 June 2026, an EU certificate is in force covering the medical device and the medical device has been manufactured and labelled, but not supplied in Australia, before 1 January 2029—1 July 2029; or
 - (ii) if, on 30 June 2026, an EU certificate is in force covering the medical device and subparagraph (i) does not apply—1 January 2029; or
 - (iii) if, on 30 June 2026, no EU certificate is in force covering the medical device and the medical device has been manufactured and labelled, but not supplied in Australia, before 1 July 2026—1 July 2029; or
 - (iv) if, on 30 June 2026, no EU certificate is in force covering the medical device and subparagraph (iii) does not apply—1 July 2026;
- (e) for a Class III medical device:
 - (i) if, on 30 June 2026, an EU certificate is in force covering the medical device and the medical device has been manufactured and labelled, but not supplied in Australia, before 1 January 2028—1 July 2029; or
 - (ii) if, on 30 June 2026, an EU certificate is in force covering the medical device and subparagraph (i) does not apply—1 January 2028; or
 - (iii) if, on 30 June 2026, no EU certificate is in force covering the medical device and the medical device has been manufactured and labelled, but not supplied in Australia, before 1 July 2026—1 July 2029; or
 - (iv) if, on 30 June 2026, no EU certificate is in force covering the medical device and subparagraph (iii) does not apply—1 July 2026;
- (f) for a Class 1 IVD medical device with a Global Medical Device Nomenclature System Code of CT944 or CT943:
 - (i) if, on 30 June 2029, an EU certificate is in force covering the medical device—1 January 2030; or
 - (ii) otherwise—1 July 2029;
- (g) for a Class 2 IVD medical device:
 - (i) if, on 30 June 2029, an EU certificate is in force covering the medical device—1 January 2030; or
 - (ii) otherwise—1 July 2029;
- (h) for a Class 3 IVD medical device:
 - (i) if, on 30 June 2028, an EU certificate is in force covering the medical device—1 January 2029; or
 - (ii) otherwise—1 July 2028;
- (i) for a Class 4 IVD medical device—1 July 2028.

medical device packaging identifier, of the packaging of a UDI medical device, means any combination of numbers, symbols and letters given to the packaging to enable identification of the device (whether or not that combination also allows identification of information relating to the device or the packaging).

retail premises means premises:

- (a) from which goods or services are available for supply, or are supplied, to a consumer; or

- (b) that are used in connection with the supply of goods or services to a consumer;
(whether or not the premises are used wholly or predominantly for that purpose).

Note: For the definition of *premises*, see subsection 3(1) of the Act.

UDI device identifier, of a UDI medical device, means any combination of numbers, symbols and letters given to the UDI medical device to enable identification of the model of the UDI medical device.

UDI issuing agency means:

- (a) the international organisation known as GS1; or
- (b) the international organisation known as the Health Industry Business Communications Council; or
- (c) the international organisation known as the International Council for Commonality in Blood Banking Automation.

UDI medical device means a medical device (other than an in-house IVD medical device) that is covered by an entry in the Register and is:

- (a) a Class I medical device that is intended by the manufacturer to be supplied in a sterile state; or
- (b) a Class IIa medical device; or
- (c) a Class IIb medical device; or
- (d) a Class III medical device; or
- (e) a Class 1 IVD medical device with a Global Medical Device Nomenclature System Code of CT944 or CT943; or
- (f) a Class 2 IVD medical device; or
- (g) a Class 3 IVD medical device; or
- (h) a Class 4 IVD medical device.

UDI production identifier, of a UDI medical device, means any combination of numbers, symbols and letters given to the UDI medical device to enable identification of production-related information for the UDI medical device.

Part 2—Application provisions

Therapeutic Goods (Medical Devices) Regulations 2002

8 In the appropriate position in Part 11

Insert:

Division 11.24—Application provisions relating to the Therapeutic Goods Legislation Amendment (Australian Unique Device Identification Database and Other Measures) Regulations 2025

11.85 Application provisions—Australian Unique Device Identification Database

- (1) The amendments of Schedule 1 made by Part 1 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (Australian Unique Device Identification Database and Other Measures) Regulations 2025* (except for the insertion of clause 13C.5 of Schedule 1 to this instrument) apply in relation to the following:
 - (a) supplies of a UDI medical device on or after the general start day for the UDI medical device;
 - (b) imports of a UDI medical device that occur after the first time, that is on or after the general start day for the UDI medical device, on which the UDI medical device is supplied for use in Australia;
 - (c) exports of a UDI medical device on or after the general start day for the UDI medical device.
- (2) Clause 13C.5 of Schedule 1 to this instrument, as inserted by Part 1 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (Australian Unique Device Identification Database and Other Measures) Regulations 2025*, applies in relation to the following:
 - (a) supplies of a UDI medical device on or after the direct marking start day for the UDI medical device;
 - (b) imports of a UDI medical device that occur after the first time, that is on or after the direct marking start day for the UDI medical device, on which the UDI medical device is supplied for use in Australia;
 - (c) exports of a UDI medical device on or after the direct marking start day for the UDI medical device.

Schedule 2—Mandatory reporting of adverse events involving medical devices

Part 1—Stage 1 amendments

Therapeutic Goods (Medical Devices) Regulations 2002

1 After Part 8

Insert:

Part 8AA—Mandatory reporting of adverse events by healthcare facilities

8AA.1 Healthcare facilities

For the purposes of paragraph (c) of the definition of *healthcare facility* in subsection 3(1) of the Act, a day-hospital facility is prescribed.

8AA.2 Reportable medical devices

For the purposes of the definition of *reportable medical device* in subsection 3(1) of the Act, the following kinds of medical devices are prescribed:

- (a) a Class III medical device;
- (b) a Class 4 IVD medical device.

8AA.3 Report requirements

Content of report

- (1) For the purposes of paragraph 41JM(5)(c) of the Act, the following information is prescribed:
 - (a) any healthcare identifier assigned to the healthcare facility under the *Healthcare Identifiers Act 2010*;
 - (b) if subsection 41JM(2) of the Act applies:
 - (i) the day of the use of the reportable medical device as mentioned in paragraph 41JM(2)(a) of the Act; and
 - (ii) the day of the death of the person as mentioned in paragraph 41JM(2)(b) of the Act or the day the serious deterioration in the health of the person as mentioned in paragraph 41JM(2)(b) of the Act is first identified; and
 - (iii) in the case of a serious deterioration in the health of the person—the nature, or a description, of that serious deterioration;
 - (c) if subsection 41JM(3) of the Act applies—the day of the intervention as mentioned in paragraph 41JM(3)(a) of the Act;
 - (d) if subsection 41JM(4) of the Act applies:
 - (i) the day of the provision of the treatment as mentioned in paragraph 41JM(4)(a) of the Act; and

- (ii) the nature, or a description, of the serious deterioration in the health of the person;
- (e) the name of the manufacturer of the reportable medical device, if known to the chief executive officer of the healthcare facility.

Timing of report

- (2) For the purposes of paragraph 41JM(6)(a) of the Act, the period prescribed is the following:
 - (a) if subsection 41JM(2) of the Act applies—the period of 10 days beginning on the day of the death of the person as mentioned in paragraph 41JM(2)(b) of the Act or the day the serious deterioration in the health of the person as mentioned in paragraph 41JM(2)(b) of the Act is first identified;
 - (b) if subsection 41JM(3) of the Act applies—the period of 45 days beginning on the day of the intervention as mentioned in paragraph 41JM(3)(a) of the Act;
 - (c) if subsection 41JM(4) of the Act applies—the period of 45 days beginning on the day of the provision of the treatment as mentioned in paragraph 41JM(4)(a) of the Act.

Manner of giving report

- (3) For the purposes of paragraph 41JM(6)(b) of the Act, the manner prescribed is an electronic form (other than fax or a scanned document).

Part 2—Stage 2 amendments

Therapeutic Goods (Medical Devices) Regulations 2002

2 Paragraphs 8AA.2(a) and (b)

Repeal the paragraphs, substitute:

- (a) a Class IIa medical device;
- (b) a Class IIb medical device;
- (c) a Class III medical device;
- (d) a Class 3 IVD medical device;
- (e) a Class 4 IVD medical device.

Schedule 3—Refund of fees

Therapeutic Goods Regulations 1990

1 After regulation 43AF

Insert:

43AG Refund of fees for certain requests relating to conditions for therapeutic goods in the Register

If, during the period beginning on 1 January 2025 and ending at the end of the day before this regulation commences, a person paid a fee covered by item 1AFA of the table in clause 3 of Schedule 9 or by item 2B of the table in Part 2 of Schedule 9A, the Secretary must refund the fee to the person.

2 Clause 3 of Schedule 9 (table item 1AFA)

Repeal the item.

3 Part 2 of Schedule 9A (table item 2B)

Repeal the item.