EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

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

The *Therapeutic Goods Act 1989* (the Act) establishes and provides for the maintenance of a national system of controls for the quality, safety, efficacy or performance, and timely availability of therapeutic goods used in, or exported from, Australia. The Act is administered by the Therapeutic Goods Administration (the TGA) within the Australian Government Department of Health and Aged Care (the Department). Subsection 63(1) of the Act enables the Governor-General to make regulations, not inconsistent with the Act, prescribing matters that are required or permitted by the Act, or necessary or convenient to be prescribed for carrying out or giving effect to the Act.

The *Therapeutic Goods Legislation Amendment (Australian Unique Device Identification Database and Other Measures) Regulations 2025* (the Amendment Regulations) amend the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations) and *Therapeutic Goods Regulations 1990* (the TG Regulations) to support implementation of:

- the unique device identification (UDI) framework for medical devices;
- the mandatory reporting of adverse events involving medical devices by healthcare facilities; and
- more minor amendments to repeal a small number of fees for applications to add, vary or remove conditions on the entry of goods in the Australian Register of Therapeutic Goods (the Register).

The UDI framework will improve the identification and traceability of medical devices and effectiveness of responses to device safety issues, by providing for the establishment of the Australian Unique Device Identification Database and requiring the inclusion in the database of device identifiers (specially designed combinations of numbers, symbols and letters for identifying medical devices or their packaging) and related information, such as manufacturer name and any warnings or precautions about their use. The Amendment Regulations require such identifiers to be provided with a device and, in some instances, marked on the device itself. These reforms will enable the TGA to work with hospitals, health practitioners, patients, pharmacies and supply chain operators, such as distributors, to more quickly identify and address unsafe medical devices.

Schedule 2 also supports medical device safety, by identifying the kinds of medical devices for which adverse events involving such devices must be reported to the TGA under the mandatory reporting scheme for healthcare facilities, and related matters. These amendments will enable the TGA to better identify trends in medical device safety and to act more quickly to protect Australian patients from unsafe products.

Schedule 3 makes a small number of more minor amendments to address a concern that some of the new fees introduced by the *Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2024*, which commenced on 1 January 2025, may not reflect the full range of circumstances or products in relation to which a request to impose, vary or remove a condition of entry in the Register may be made.

In relation to consultation on the UDI framework, three public consultations were conducted between 2019 and 2022, as well as a consultation under the WTO Agreement on Technical Barriers to Trade in 2022 and numerous industry working groups and workshops between July 2020 and December 2024. Overall stakeholders, including sponsors and manufacturers, health professionals, peak bodies, clinical quality registries, state health departments and consumer representatives, support the implementation of the UDI framework. The UDI framework is consistent with those being implemented in other comparable countries.

In relation to consultation on device adverse event reporting, the TGA consulted publicly between 18 October and 13 December 2021. Fifty-six submissions were received, including from state and territory governments, private and day hospitals, healthcare professionals, industry, and consumer representatives, with the majority supportive. Further consultation occurred across six stakeholder roundtables between May to September 2023, and in February 2024 an Interjurisdictional Steering Committee was established to discuss implementation strategies with representatives from the Australian Commission on Safety and Quality in Health Care, jurisdictions, private and day hospitals, the Australian Medical Association and the Royal Australian College of Medical Administrators.

In relation to the minor amendments to fees, the TGA has flagged the changes with the Generic and Biosimilar Medicines Association (GBMA), who did not raise concerns.

A regulatory impact statement was undertaken in relation to the establishment of a UDI framework and was published on 6 October 2020. An impact analysis for the mandatory reporting of medical device adverse events was undertaken, which the Office of Impact Analysis (OIA) determined was consistent with good practice (OBPR22-02137). These analyses will be made available on the OIA website at: oia.pmc.gov.au/published-impact-analyses-and-reports. The OIA also advised that an impact analysis was not required in relation to the fee amendments (OIA24-08791).

The Act specifies no conditions that need to be satisfied before the power to make the Amendment Regulations may be exercised. The Amendment Regulations are a legislative instrument for the purposes of the *Legislation Act 2003*.

The Amendment Regulations commence on the day after registration on the Federal Register of Legislation, except for Schedule 2, of which Part 1 commences on 21 March 2026, and Part 2 commences on 1 April 2028.

Details of the Amendment Regulations are set out in **Attachment A**. The Amendment Regulations are compatible with human rights and freedoms recognised or declared under section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. A full statement of compatibility is set out in **Attachment B**.

Authority: Subsection 63(1) of the
Therapeutic Goods Act 1989

ATTACHMENT A

Details of the proposed *Therapeutic Goods Legislation Amendment (Australian Unique Device Identification Database and Other Measures) Regulations 2025*

Section 1 - Name

This section provides that the title of the proposed regulations is the *Therapeutic Goods Legislation Amendment (Australian Unique Device Identification Database and Other Measures) Regulations 2025* (the Amendment Regulations).

Section 2 - Commencement

This section provides that the Amendment Regulations commence on the day after registration on the Federal Register of Legislation, except for Schedule 2, of which Part 1 commences on 21 March 2026, and Part 2 commences on 1 April 2028.

Section 3 - Authority

This section provides that the Amendment Regulations are made under the *Therapeutic Goods Act 1989* (the Act).

Section 4 - Schedules

This section provides that 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

Item [1] – After Part 9

This item introduces a new Part 9A to the MD Regulations. Part 9A sets out the requirements relating to establishing, maintaining and dealing with information that is included in, the Australian Unique Identification Database.

9A.1 Australian Unique Device Identification Database

Subregulations 9A.1(1) and (2) provide that for the purposes of section 41CE of the Act, the Secretary must cause for a database to be established, to be known as the Australian Unique Device Identification Database.

Subregulation 9A.1(3) requires the Secretary to either:

- maintain the whole of the database; or
- on behalf of the Commonwealth, enter into a written agreement with a person to maintain the whole of the database; or
- 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.

Subregulation 9A.1(4) requires that the database must not include personal information, unless the personal information:

- relates to the name of a person to whom a kind of medical device is included in the Australian Register of Therapeutic Goods (the Register);
- is about an authorised representative of the manufacturer of a kind of medical device; or
- is about an authorised representative of a person in relation to whom a kind of medical device is included in the Register.

This reflects that the information in the database will principally be focused on the medical devices themselves and related information, rather than on persons. The only personal information likely to be included in the database would be information that forms part of the name of a device sponsor or manufacturer, for instance “John Smith Devices”, though this only applies in relation to a very small number of sponsors or manufacturers. In such instances, it is likely such information would already be in the public domain as part of the promotion of such devices or manufacturing services. Although new subregulation 9A.1(4) does not preclude the inclusion of personal information about an authorised representative of a sponsor or manufacturer, new subregulation 9A.1(5) provides that such information must not be included in the database unless the authorised representative consents to that inclusion. Further, in practice the TGA would not include this information in the database.

Subregulations 9A.1(6) and (7) require that the information that is included in the database in relation to UDI medical device that are a type of model covered by a suspension under Part 4-6 of the Act or a cancellation under Part 4-6 of the Act respectively, must not be removed from the database during the period of suspension, or following the cancellation, unless the Secretary is satisfied that it is appropriate in all the circumstances to do so.

It is important for this information to be retained even if the UDI medical device is suspended or cancelled, to ensure that sponsors and manufacturers can be contacted in the event of a safety concern associated with the device, to support the identification and traceability of the relevant medical devices. UDI medical device is a defined term in the Amendment Regulations and explained below.

Subregulations 9A.1(8) to (11) deal with the removal of information from the database in specified circumstances. Subregulation 9A.1(8) permits the Secretary to remove information from the database in relation to UDI medical devices that are type of model if the information is not information that is required by the MD Regulations to be included in the database and a sponsor or manufacturer of those medical devices has requested the Secretary to remove the information.

Subregulation 9A.1(9) provides the Secretary with a discretion to 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. As detailed in item 2, this decision would be subject to merits review by the Minister, and subsequently, the Administrative Review Tribunal.

Subregulation 9A.1(10) requires the Secretary to remove personal information that is not personal information covered by new subregulation 9A.1(4). This further ensures that only personal information that is critical to supporting identification and traceability of medical devices is included in the database. Subregulation 9A.1(11) also requires the Secretary to remove personal information about an authorised representative of a sponsor or manufacturer if the authorised representative requests its removal.

Subregulation 9A.1(12) allows the Secretary to correct information in the database in certain circumstances, being where the Secretary is satisfied that it is either:

- 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
- in the interests of public health or safety for the Secretary to do so.

An example of a correction anticipated to be undertaken by the Secretary is where bulk changes are required to be made to a sponsor’s data, due to the large volumes of device data in the database, and it would be more practical for the Department to make these changes than the sponsor themselves.

Subregulation 9A.1(13) permits the Secretary to arrange to make the whole or a part of the database to be made available, with the exception of personal information covered by paragraphs 41CE(2)(b) or (c), which relates to an authorised representative of a sponsor or manufacturer.

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

This item amends subregulation 10.7(1) to include in the list of decisions that comprise the definition of '*initial decision*' for the purposes of regulation 10.7 a decision made under new subregulation 9A.1(9) to remove information from the database that the Secretary is satisfied is incomplete or incorrect. The effect is that a person whose interests are affected by such a decision may request that the Minister (or delegate) reconsider the decision, with a further right to seek review of any such reconsideration decision by the Administrative Review Tribunal.

Item [3] – Part 2 of Schedule 1 (heading)

This item repeals the existing heading of Part 2 of Schedule 1 and replace it with the '*Other Principles*', to more accurately capture the proposed content of Part 2 of Schedule 1 to the MD Regulations.

Item [4] – After clause 13.4 of Schedule 1

This item introduces new clauses 13.5 and 13.6 to the MD Regulations. These clauses introduce requirements for the UDI device identifier, UDI production identifier and medical device packaging identifier to be provided with a UDI medical device. These terms are defined in the dictionary to the MD Regulations.

Clauses 13.5 and 13.6 refer to identifiers being in human-readable form and machine-readable form. Machine-readable form refers to the identifier being provided in a form that supports identification or entering of the identifier directly into a computer system, without human involvement. This may include Automatic Identification and Data Capture (AIDC) methods, and can include bar codes, Quick Response (QR) codes, smart cards, biometrics and radio-frequency identification (RFID). Human readable form refers to the identifier being in a form that has a legible interpretation of the identifier in letters and numbers that a human is able to read.

Clause 13.5 – UDI device identifier and UDI production identifier

Subclause 13.5(1) requires that for UDI medical devices, the UDI device identifier and the UDI production identifier of the UDI medical device, must be provided with the UDI medical device. Subclauses 13.5(2) and (3) provide for how these identifiers are to be provided with the device.

Subclause 13.5(2) provides for the requirements for providing the identifiers with a UDI medical device, for all UDI medical devices. However, in accordance with subclause 13.5(3), from the relevant direct marking start day, UDI medical devices to which clause 13C.5 applies (these are UDI medical devices that are intended by their manufacturer to be reprocessed between uses on different patients) will *no longer* be required to comply with requirements in subclause 13C.5(2), and *instead will be required to comply with subclause 13.5(3)*. The general start day and direct marking start day are defined in item 7 by reference to specified dates for specified kinds of UDI medical devices expected to apply to UDI medical devices as detailed in item 7.

In accordance with subclause 13.5(2), the UDI device identifier and the UDI production identifier must be provided on the relevant UDI medical device itself. However, if it is impracticable or inappropriate to provide the identifiers on the device itself, the identifiers must be provided in human-readable form and machine-readable form: on the packaging used for the UDI medical device. Alternatively, if the UDI medical device is packed together with other such UDI medical devices because individual packaging of the UDI medical device for supply is not practicable, the identifiers must be provided on the outer- packaging used for the UDI medical devices.

Further, if it is impracticable or inappropriate to provide the identifiers on the device itself, or on the packaging used for the UDI medical device, the identifiers must be provided in human readable form and machine-readable form:

- if the UDI medical device is not software—on a leaflet supplied with the UDI medical device; or
- if the UDI medical device is software—on a leaflet supplied with the UDI medical device, or provided electronically. An example of providing the relevant identifiers electronically would be providing this information in machine-readable and human-readable form on a website that can be accessed by a patient.

For a UDI medical device to which new clause 13C.5 applies, new subclause 13.5(3) provides that, from the relevant direct marking start date for the device, new subclause 13.5(2) ceases to apply and, instead, an identifier in human-readable form and machine-readable form must be provided:

- on the packaging used for the UDI medical device; or
- if the UDI medical device is packaged together with other UDI medical devices because individual packaging of the UDI medical devices for supply is not practicable, the identifiers must be provided on the outer packaging used for the UDI medical device.

Further, if it is impracticable or inappropriate to comply with paragraph 13.5(3)(a), each identifier, in human-readable form and machine-readable form, must be provided on a leaflet supplied with the UDI medical device.

Subclause 13.5(4) provides that if a UDI medical device is intended by the manufacturer to be supplied at retail premises, the UDI production identifier of the UDI medical device in machine-readable form in not required to be provided with the device.

Item 7 defines ‘retail premises’ as premises:

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

Clause 13.6 UDI medical devices – medical device packaging identifier

Subclause 13.6(1) requires that if a type of packaging is used for UDI medical devices that are a type of model, the medical device packaging identifier of the packaging of the UDI medical device must be provided with the UDI medical device. Subclause 13.6(2) provides that the packaging identifier must be provided in both human-readable form and machine-readable form on the packaging of the UDI medical device.

This amendment recognises that particularly when part of the supply chain, medical devices are often packaged in specific ways, and that traceability of medical devices by packaging level may help identify unsafe devices more quickly and effectively, preventing those devices from being used and potentially causing harm to patients or others such as health practitioners.

Item [5] – Paragraphs 13A.2(1)(a) and (b) of Schedule 1

These items repeal current paragraphs 13A.2(1)(a) and (b) of the MD Regulations and substitute them with new paragraphs that include requirements for the inclusion of a UDI device identifier and UDI production identifier on a patient implant card provided with a UDI medical device.

Subclause 13A.2(1) currently requires that either a patient implant card that includes the information covered by subclause 13A.2(2) must be made available to a patient to whom an implantable medical device of a kind to which clause 13A of Schedule 1 to the MD Regulations applies, or that the same information in electronic form must be made available to the patient in a way that is readily accessible.

The amendments have the effect that the UDI device identifier and UDI production identifier of UDI medical device to which clause 13A of Schedule 1 to the MD Regulations applies, in both human-readable form and machine-readable form, must be made available for the patient concerned either:

- on a card, being the patient implant card; or
- made available electronically in way that is readily accessible for the patient concerned.

Item [6] – After clause 13B of Schedule 1

This item inserts new clause 13C which provides for requirements in relation to the inclusion in the database of unique device identifiers of medical devices and information relating to those unique device identifiers for UDI medical devices.

Clause 13C.1 Identifiers relating to UDI medical devices

Subclauses 13C.1(1) to (4) introduce requirements for the UDI device identifier, UDI production identifier and medical device packaging identifier relating to a UDI medical device to be issued by or in accordance with any applicable requirements of an UDI issuing agency (item 7 introduces a definition of the term ‘UDI issuing agency’).

This amendment ensures that the unique device identifiers that are used in Australia and included in the database are globally unique and mirror the identifiers that are used in major overseas jurisdictions such as the United States (US) and the European Union (EU). The

issuing agencies issue a series of numeric or alphanumeric characters created through a globally accepted device identification and coding standard, which are applied to specific models and package configurations of UDI medical devices.

Global consistency of unique device identifiers is very important, as Australia is a small proportion of the global medical devices market, and the majority of devices supplied in Australia are manufactured overseas and also supplied in major jurisdictions such as the US and the EU. Therefore, it is intended that the unique device identifiers are consistent with these global markets, to reduce regulatory burden on manufacturers who supply to multiple markets and to mitigate the risk of medical device supply disruptions in Australia.

Subclause 13C.1(1) requires that 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.

The UDI device identifier is intended to be a numeric or alphanumeric character that is specific to the model and any relevant packaging of the medical device.

Subclause 13C.1(2) requires that 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.

The UDI production identifier is intended to be a numeric or alphanumeric code that identifies the unit of device production, which may include identifiers such as the lot or batch within which a device was manufactured, the serial number of the device, the expiration date of device, the date of manufacture, or where relevant, the version number of software that is a medical device.

Subclause 13C.1(3) requires that 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.

Subclause 13C.1(4) requires that in relation to UDI medical devices that are a type of model, the identifiers covered in subclauses (1) to (3) must have been issued by the same UDI issuing agency.

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

Clauses 13C.2 and 13C.3 introduce requirements for certain information to be included in the database, which would include UDI device identifiers, packaging identifiers, and other information related to UDI medical devices.

Subclause 13C.2(1) require that for UDI medical devices that are a type of model, both the UDI device identifier of these devices and the name of the UDI issuing agency that issued the UDI device identifier must be included in the database. The note to subclause 13C.2(1) clarifies that the circumstances in which there is a different type of model of medical devices are set out in subclause 13C.2(5).

Subclause 13C.2(2) requires that for UDI medical devices that are a type of model and are packaged, the medical device packaging identifier of that packaging must also be included in the database.

Subclause 13C.2(3) requires that the information covered in proposed subclause 13C.2(1) must be included in the 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. For example, if a Class I medical device that is supplied in a sterile state is first supplied on 1 April 2029 (noting that this would be after the general start date for such devices, as the general start date for such Class I devices will be 1 January 2029 or 1 July 2028, depending on the circumstances), then the UDI device identifier and the name of the UDI issuing agency that issued the UDI device identifier would be required to be included in the database before the end of 1 May 2029.

Subclause 13C.2(4) provides that information covered in proposed subclause 13C.2(2) (namely, the medical device packaging identifier) must be included in the 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, For example, if a Class I medical device that is supplied in a sterile state is first supplied with new packaging on 1 April 2030, then the relevant medical device packaging identifier must be included in the database before the end of 1 May 2030.

The general start day for the UDI medical devices is proposed to be defined in the Dictionary of the MD Regulations, as detailed in item 7.

Subclauses 13C.2(5), (6) and (7) provide when a UDI medical device is a different type of model.

Subclause 13C.5 lists several kinds of changes that, if they occur to or in relation to a model of a UDI medical device, would be a ***relevant change*** that result in the medical devices being taken to be a different type of model. These include, for instance:

- 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;
- the labels for the medical devices, or information provided with the medical devices, state that the medical devices contain latex; or
- a change to the magnetic resonance imaging safety status of the medical devices.

The amendment has the effect of stipulating that if any of these types of changes occur the UDI medical device will be taken to be a different type of model, and a new UDI device identifier and UDI production identifier will be required.

Subclause 13C.2(6) provides that if two or more relevant changes occur in relation to a model of UDI medical device as part of the same change in production of the device, then those medical devices, as affected by the two or more relevant changes, are taken to be a (single) different type of model. This has the effect of only requiring one new set of UDI device identifier and new UDI production identifier to be generated, rather than two, in such circumstances. For example, if a UDI medical device brand name changes and the model number changes, as provided for in paragraphs (h) and (i) of proposed subclause 13C.2(5),

but these changes are implemented in the same production of the device, then the model, with the new brand name and model number, would be considered a single, different type of model (not two separate types of models).

Subclause 13C.2(7) clarifies that the changes specified in subclause 13C.2(5) do not limit the circumstances in which there may be a different type of model of UDI medical devices.

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

Clause 13C.3 lists other information related to the UDI medical device that would be required to be included in the database and the timing for when this information must be included.

For instance, subclause 13C.3(1) requires the inclusion in the database of the following in relation to a UDI medical device:

- the identification number that is allocated to the manufacturer by the TGA. This is proposed to be required to enable accurate identification of a manufacturer, and to help address any potential issues where a manufacturer name is changed over time, or is entered inconsistently in the database if it is left as a free text field;
- the brand name of the device; and
- any special operating instructions for use of the device.

For the avoidance of doubt, whether a device is a type of kit is not intended to refer to 'kits' as described in section 7B of the Act. It is intended that this would refer to where medical devices are a collection of products that are packaged together to achieve a common intended use and are distributed as a medical device.

Subclause 13C.3(2) requires that, if a clinical size type of a UDI medical device is included in the database, then the clinical size value and the clinical size unit of measure of that medical device must also be included in the database.

Subclause 13C.3(3) deals with the timing of when such information must be included in the database, and provides that the information required to be included in the database in accordance with new subclauses 13C.3(1) and (2) must be included in the database within 30 days of the first day, on or after the general start day for the UDI medical device, that the device is supplied for use in Australia. For example, if a medical device is first supplied on 1 April 2029, and this is on or after its general start day (as defined by item 7), then the relevant information must be included in the database before the end of 1 May 2029.

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

Clause 13C.4 requires that information that is included in the database must be accurate and up to date.

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

Subclause 13C.5(1) requires that the UDI device identifier and UDI production identifier is to be directly marked on devices that are intended by the manufacturer to be reprocessed between different patients, and that this must be done by the manufacturer in both human-readable and machine-readable forms unless it is impracticable or inappropriate to do so.

However, subclause 13C.5(2) provide that compliance with the new subclause 13C.5(1) not be required where:

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

For example, where a UDI medical device is to be reprocessed between different patients, but is of such size that it would be considered too small for the UDI device identifier and UDI production identifier to be directly marked on the device itself, new paragraph 13C.5(2(d) would apply, and it would not be necessary for these identifiers to be marked on that device. However, it is intended that where an exception would apply and the UDI device identifier and UDI production identifier are not required to be directly marked on a medical device, these identifiers are still required to be provided with the device in accordance with new subclause 13.5.

Item [7] – Dictionary

This item introduces a number of important new definitions in the Dictionary in the MD Regulations underpinning these reforms.

This item provides that ***direct marking start day*** for a UDI medical device means the following day:

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

This definition of ***direct marking start day*** is intended to provide a staggered commencement of the requirements to directly mark UDI medical devices to which proposed clause 13C.5 applies, depending on the class of the medical device.

This item provides that an ***EU certificate*** means an overseas regulator conformity assessment document issued under either:

- Council Directive 93/42/EEC of the Council of the European Communities, as in force from time to time; or
- Directive 98/79/EC of the European Parliament and the Council of the European Union, as in force time to time.

These directives are generally publicly available for free and may be accessed at eur-lex.europa.eu/homepage.html?lang=en.

This item provides that ***general start day***, for a UDI medical device means the following day as outlined below:

Class of UDI medical device	**Specified circumstances**	**General start date**
Class I medical device	if, on 30 June 2028, an EU certificate is in force covering the medical device the device is not covered by an EU certificate	1 January 2029 1 July 2028
Class I medical device that is supplied in a sterile state	if, on 30 June 2028, an EU certificate is in force covering the medical device otherwise	1 January 2029 1 July 2028
Class IIa medical device	if, on 30 June 2027, an EU certificate is in force covering the medical device otherwise	1 January 2029 1 July 2027
Class IIb medical device that is an implantable medical device	if, on 30 June 2026, an EU certificate is in force covering the medical device, and the medical device was manufactured and labelled but not supplied in Australia before 1 January 2028 if, on 30 June 2026, an EU certificate is in force covering the medical device and medical device was not manufactured and labelled before 1 January 2028 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 if, on 30 June 2026, no EU certificate is in force covering the medical device and the medical device was not manufactured and labelled before 1 July 2026	1 July 2029 1 January 2028 1 July 2029 1 July 2026

Class of UDI medical device	Specified circumstances	General start date
Class IIb medical device that is not an implantable medical device	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
	if, on 30 June 2026, an EU certificate is in force covering the medical device and the medical device was not manufactured and labelled before 1 January 2029	1 January 2029
	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
	if, on 30 June 2026, no EU certificate is in force covering the medical device and the medical device was not manufactured and labelled before 1 July 2026	1 July 2026
Class III medical device	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
	if, on 30 June 2026, an EU certificate is in force covering the medical device and the medical device was not manufactured and labelled before 1 January 2028	1 January 2028
	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
	if, on 30 June 2026, no EU certificate is in force covering the medical device and the medical device was not manufactured and labelled before 1 July 2026	1 July 2026
Class 1 IVD medical device with a Global Medical Device Nomenclature System Code of CT944 or CT 943	if, on 30 June 2029, an EU certificate is in force covering the medical device	1 January 2030
	the device is not covered by an EU certificate	1 July 2029
Class 2 IVD medical device	if, on 30 June 2029, an EU certificate is in force covering the medical device	1 January 2030
	the device is not covered by an EU certificate	1 July 2029
Class 3 IVD medical device	if, on 30 June 2028, an EU certificate is in force covering the medical device	1 January 2029

Class of UDI medical device	Specified circumstances	General start date
	the device is not covered by an EU certificate	1 July 2028
Class 4 IVD medical device	in all circumstances	1 July 2028

The definition of general start day has the effect of providing a staggered commencement depending on the class of the medical device, and whether certain EU conformity evidence is in place in respect of the device. If an EU certificate (as defined) is in place in respect of a UDI medical device, this signifies in most instances that the manufacturer of the medical device has not yet transitioned to more up to date evidence about the quality of their manufacturing processes as part of medical device manufacturing reforms in Europe, with the effect that there is likely to be a need for more time for manufacturers and sponsors of such devices to prepare for a range of medical device reforms in Australia, including the UDI reforms.

This item introduces a definition of a ***UDI medical device***, being a medical device (other than an in-house IVD medical device) that is covered by an entry in the Register and that is a:

- Class I medical device that is intended by the manufacturer to be supplied in a sterile state;
- Class IIa medical device;
- Class IIb medical device;
- Class III medical device;
- Class 1 IVD medical device with a Global Medical device Nomenclature System Code of CT944 or CT943;
- Class 2 IVD medical device;
- Class 3 IVD medical device; or
- Class 4 IVD medical device.

The above types of medical devices are defined in the dictionary at the end of the MD Regulations. New subclause 13C.1(6) also clarifies that in-house IVD devices are not UDI medical devices as described in new subclause 13C.1(5). This subclause mean that in-house IVD devices are not required to comply with the UDI framework.

This item also provides that ***retail premises*** means premises:

- from which goods or services are available for supply, or are supplied, to a consumer, (for instance, this may include a supermarket or, convenience store); or
- 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).

The definition of retail premises is necessarily broad to capture the array of premises from which a UDI medical device may be supplied to consumers. The note to this definition indicates that there is an existing definition of ‘premises’ contained in subsection 3(1) of the Act.

Part 2–Application provisions

Part 2 of this Schedule provides for application arrangements in relation to the amendments that are made to the MD Regulations by Part 1 of this Schedule.

Therapeutic Goods (Medical Devices) Regulations 2002

Item [8] – In the appropriate position in Part 11

This item introduces new Division 11.24 in the MD Regulations to provide for the application of the amendments to the MD Regulations that are made by Part 1 of Schedule 1 to the Amendment Regulations.

Subregulations 11.85(1) and (2) of the MD Regulations provides that the amendments of Schedule 1 made by Part 1 of Schedule 1 to the Amendment Regulations would apply as follows:

- to the supply of a UDI medical device on or after the general start day or direct marking start day (as applicable) for the UDI medical device;
- to imports of a UDI medical device that occur after the first time, that is on or after the general start day or direct marking start day (as applicable) for the UDI medical device, on which the UDI medical device is supplied for use in Australia; and
- to exports of a UDI medical device on or after the general start day or direct marking start day (as applicable) for the UDI medical device.

For example:

- the general start day for a Class I medical device that is supplied in a sterile state for which an EU certificate is in force on 30 June 2028 is 1 January 2029;
- if the first day on which such a Class I medical device is supplied for use in Australia were 1 March 2029;
- the amendments made by Part 1 of Schedule 1 to the proposed Regulations would apply to the supply or export of such a device on or after 1 January 2029 (being the general start day), and to any imports of the device after 1 March 2029 (as this was the first time supply occurred in Australia after the general start day).

Schedule 2—Mandatory reporting of adverse events involving medical devices

Part 1–Stage 1 amendments

Therapeutic Goods (Medical Devices) Regulations 2002

Item [1] - After Part 8

This item introduces a new Part 8AA to the MD Regulations, which provide for certain critical elements of the scheme for the mandatory reporting of adverse events involving medical devices by healthcare facilities that is set out in Schedule 1 to the *Therapeutic Goods Amendment (2022 Measures No. 1) Act 2023* (the Amendment Act). Schedule 1 to the Amendment Act will commence on 21 March 2025. These elements include prescribing healthcare facilities other than public and private hospitals to which the scheme will apply, the kinds of medical devices for which an adverse event must be reported and certain kinds of information that must be included in such a report.

Taken together with the Amendment Act measures commencing on 21 March 2025, these reforms will improve the identification of trends in medical device safety, ensuring earlier detection of potential device safety issues and better protecting Australian patients from unsafe devices. A staged approach to the reforms is proposed, based on the reporting of the most serious adverse events initially, followed by the reporting of adverse events involving other important types adverse events in 2028.

Regulation 8AA.1 Healthcare facilities

Regulation 8AA.1 prescribes that a day hospital is a healthcare facility for the purposes of paragraph 3(1)(c) of the Act.

Relevantly, from 21 March 2025 following the commencement of Schedule 1 to the Amendment Act, subsection 3(1) of the Act will introduce the following definition of a healthcare facility:

- a public hospital;
- a private hospital; or
- any other facility prescribed by regulations made for the purposes of this paragraph.

A day hospital is intended to include licenced and accredited free-standing facilities, that are physically separated from and not integrated with an overnight hospital, and that admit patients for medical or surgical treatment for periods not more than 24 hours.

The amendment makes it mandatory for day hospitals, along with public and private hospitals, to report relevant adverse events relating to medical devices. The reason such day hospitals are proposed to be included as part of the new scheme is that they fall under a health service that is responsible for clinical governance and delivery of care in a specified location.

Regulation 8AA.2 Reportable medical devices

This regulation prescribes that a Class III medical device and a Class 4 IVD medical device are reportable medical devices for the purposes of the definition of that term in subsection

3(1) of the Act, following the commencement of Schedule 1 to the Amendment Act on 21 March 2025 (Schedule 1 introduces a number of key definitions for the purposes of the new scheme, including 'reportable medical device').

Relevantly, subsection 3(1) of the Act will introduce a definition of a reportable medical device, which provides that a reportable medical device means a medical device of a kind prescribed by regulations made for the purposes of this definition.

Class III medical devices and Class 4 IVD medical devices are to be defined as reportable medical devices in Stage 1 of these reforms because these classes of medical devices carry a higher potential severity of harm for users.

Regulation 8AA.3 Report requirements

This regulation prescribes the information that needs to be included in the content for a report that is made by the chief executive officer of a healthcare facility to the Secretary in relation to a reportable medical device and a person, as well as the timeframe and manner of the reporting.

Content of report

Relevantly, paragraphs 41JM(5)(a) and (b), added to the Act by the Amendment Act and commencing on 21 March 2025, provide that a report about adverse events involving reportable medical devices must include the name or description of the reportable device, a description of the matters covered by new subsections 41JM(2), (3) or (4) of the Act and any other information prescribed by regulations for the purposes of paragraph 41JM(5)(c) . Subregulation 8AA.3(1) prescribes additional information for this purpose, to ensure that the TGA is able to access meaningful information about an adverse event that will enable it to detect and act on of potential device safety issues.

Paragraph 8AA.3(1)(a) prescribes that the healthcare provider identifier, assigned to the healthcare facility under the *Healthcare Identifiers Act 2010*, must be included by the healthcare facility in a report regarding the reportable medical device. This amendment ensures the accurate identification of healthcare facilities where an incident has occurred, and avoid confusion or potential issues with facility names that may change over time.

The Amendment Regulations are limited by the circumstances in which a report in relation to adverse events involving reportable medical devices will be required under section 41JM of the *Therapeutic Goods Amendment (2022 Measures No. 1) Act 2023.* The Amendment Regulations only authorise the disclosure of certain personal information where a medical device has resulted, or would result in, the death or serious deterioration in health of a person. That information is the time and/or the nature or description of the person's death or serious deterioration in the person's health, or intervention of the person in a healthcare facility, in limited circumstances outlined under section 41JM of the *Therapeutic Goods Amendment (2022 Measures No. 1) Act 2023*.

The TGA, as part of the Department, is an APP entity for the purposes of the *Privacy Act 1988* (the Privacy Act). Consequently, the collection or use of personal information must be consistent with the Privacy Act. The Department's privacy policy applies generally to this information.

Paragraph 8AA.3(1)(b) provides that if new subsection 41JM(2) of the Act applies (i.e. where a reportable medical device is used in the facility and the use of the device has resulted in the death, or a serious deterioration in the health of a person while the device is used in the facility) then the following information must be included in the report:

- the day of the use of the reportable medical device, in accordance with paragraph 41JM(2)(a) of the Act; and
- the day of the death of the person or the day the serious deterioration in the health of the person was first identified, as mentioned in paragraph 41JM(2)(b) of the Act; and
- in the case of a serious deterioration in the health of a person, the nature, or a description, of that serious deterioration.

This additional information is particularly important because of the seriousness of such adverse events, and the importance of identifying the cause and acting as quickly as possible to prevent any similar events for other patients.

Paragraph 8AA.3(1)(c) provides that, if subsection 41JM(3) of the Act applies, (i.e. where a reportable medical device is not used in the facility because of the intervention of a person in the facility, and the use of the device, if the device were used, would result in, or would be likely to result in, the death, or a serious deterioration in the health of a person), then the day of intervention needs to be included in the report. This additional information would be required because of the potential for the adverse event that was prevented to occur and lead to a life-threatening or serious health outcome for another patient.

Paragraph 8AA.3(1)(d) provides that, if subsection 41JM(4) of the Act applies, (i.e. where a health practitioner provides treatment to a person in the facility for a serious deterioration in the health of the person, and the use of a reportable medical device has resulted in the serious deterioration in the health of the person – this is where the adverse event itself has already occurred before the person attends the facility), then the following information must be included in the report:

- the day of the provision of the treatment; and
- the nature or a description, of the serious deterioration in the health of the person.

This additional information is important to help identify the cause of the adverse event and to the steps required to prevent similar events for other patients.

Paragraph 8AA.3(1)(e) prescribe that the name of the manufacturer of the reportable medical device, if known to the chief executive officer of the healthcare facility, must also be in the report, regardless of which type of adverse event as described in new section 41JM is involved.

Timing of the report

New subsection 41JM(6) of the Act provides that the report must be given to the Secretary within the period prescribed by the regulations, or within such longer period as the Secretary allows in a particular case. Subregulation 8AA.3(2) prescribes applicable timeframes for this purpose.

Paragraph 8AA.3(2)(a) provides that, if subsection 41JM(2) of the Act applies (i.e. where a reportable medical device is used in the facility, and the use of the device has resulted in the death, or a serious deterioration in the health of a person while the device is used in the facility), then the report must be given to the Secretary within the period of 10 days beginning on the day of the death of the person or the day the serious deterioration in the health of the person is first identified, as mentioned in paragraph 41JM(2)(b) of the Act. This shorter-time frame for reporting reflects the seriousness of such events and the importance of taking steps to prevent similar incidents.

Paragraph 8AA.3(2)(b) provides that, if subsection 41JM(3) of the Act applies (i.e. where a reportable medical device is not used in the facility because of the intervention of a person in the facility, and the use of the device, if the device were used, would result in, or would be likely to result in, the death, or a serious deterioration in the health of a person), then the report must be given to the Secretary within the period of 45 days beginning on the day of the intervention, as mentioned in paragraph 41JM(3)(a) of the Act. This would allow healthcare facilities to provide "batch" reports of such adverse events, every 45 days.

Paragraph 8AA.3(2)(c) provides that, if subsection 41JM(4) of the Act applies (i.e. where a health practitioner provides treatment to a person in the facility for a serious deterioration in the health of the person, and the use of a reportable medical device has resulted in the serious deterioration in the health of the person), then the report must be given to the Secretary within 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. This would similarly allow healthcare facilities to provide adverse event reports on a "batch" basis, every 45 days.

Manner of giving report

New paragraph 41JM(6)(b) of the Act provides that a report must be given to the Secretary in the manner prescribed by regulations made for the purposes of that paragraph. Accordingly, subregulation 8AA.3(2) prescribes that the report about adverse events involving reportable medical devices must be given to the Secretary in an electronic form (other than fax or a scanned document).

Part 2–Stage 2 amendments

Therapeutic Goods (Medical Devices) Regulations 2002

Part 2 of this Schedule provides for further amendments that are proposed to commence on 1 April 2028, bringing additional medical devices into the mandatory reporting of adverse events scheme.

Item [2] - Paragraphs 8AA.2(a) and (b)

This item repeals paragraphs 8AA.2(a) and 8AA.2(b), introduced by Stage 1, to prescribe that a Class IIa medical device, a Class IIb medical device, a Class III medical device, a Class 3 IVD medical device, and a Class 4 IVD medical device are also reportable medical devices for the purpose of subsection 3(1) of the Act.

Relevantly, subsection 3(1) of the Act, as amended by the Amendment Act from 21 March 2025, will introduce a definition of a reportable medical device, which provides that a

reportable medical device means a medical device of a kind prescribed by regulations made for the purposes of this definition.

The Stage 2 amendments have the effect of adding Class IIa medical devices, Class IIb medical devices, and Class 3 IVD medical devices to the definition of a reportable medical device, and in turn to the medical devices mandatory reporting scheme. These amendments are designed to include types of medical devices that have a potential severity of harm if an adverse event were to occur.

The Stage 2 amendments commence from 1 April 2028, to allow for the mandatory reporting scheme to be implemented in tranches. This staged approach provides for an initial transition period for facilities to undertake any required system changes, ensure interoperability of data systems, and to develop related data de-identification methods. It is intended to allow healthcare facilities to prepare and establish the necessary operating procedures, conduct staff training and implement processes to monitor compliance. Phasing also allows for any initial challenges identified during the transition period to be addressed in future phases.

Schedule 3—Refund of fees

Therapeutic Goods Regulations 1990

Item [1] - After regulation 43AF

This item introduces a mechanism to require the Secretary to refund any fees paid by sponsors in accordance with table item 1AFA in clause 3 of Schedule 9 and table item 2B in Part 2 of Schedule 9A of the TG Regulations, between 1 January 2025 and the end of the day before the proposed Regulations commence.

The introduction of such a refund mechanism seeks to address concerns that these fees, introduced by the *Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2024* (the Amendment Regulations), may not reflect the range of circumstances or therapeutic goods in relation to which a request to impose a new condition of entry in the Register, or to vary or remove an existing such condition, may be made, and could potentially result in an over-recovery or under-recovery in some product categories.

This item ensures that sponsors that may have complied with the Amendment Regulations and paid a fee during the period specified will not be adversely impacted and that any moneys paid are refunded to the person.

Items [2] and [3] - Clause 3 of Schedule 9 (table item 1AFA) and Part 2 of Schedule 9A (table item 2B)

These items amends clause 3 of Schedule 9 to the TG Regulations to repeal table item 1AFA, and Part 2 of Schedule 9A to the TG Regulations to repeal table item 2B, to repeal the fees involved.

Relevantly, table item 1AFA in clause 3 of Schedule 9 and table item 2B in Part 2 of Schedule 9A to the TG Regulations introduce a new fee relating to requests by persons in relation to whom therapeutic goods are registered, listed or, in respect of a biological, is included in the Australian Register of Therapeutic Goods, to impose a new condition of registration, listing or inclusion, or to vary or remove an existing condition, for the purposes of subsections 28(3A) or 32EE(2) of the Act.

The repeal of these fee items will allow time for more detailed analysis before canvassing with therapeutic goods sponsors any proposal to introduce a more comprehensive set of fees relating to such requests.

ATTACHMENT B

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*

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

This disallowable legislative instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the legislative instrument

The object of the *Therapeutic Goods Act 1989* (the Act) is to establish and maintain a national system of controls for the quality, safety, efficacy or performance, and timely availability of therapeutic goods that are used in Australia or exported from Australia. The Therapeutic Goods Administration (the TGA), which is part of the Department of Health and Aged Care (the Department), is responsible for administering the Act.

Subsection 63(1) of the Act provides that the Governor-General may make regulations, not inconsistent with the Act, prescribing matters required or permitted to be prescribed by the Act or necessary or convenient to be prescribed for carrying out or giving effect to the Act. Relevantly, the regulations may prescribe fees in respect of matters under the Act, or the regulations made under the Act.

The *Therapeutic Goods Legislation Amendment (Australian Unique Device Identification Database and Other Measures) Regulations 2025* (the Amendment Regulations) amend the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations) and *Therapeutic Goods Regulations 1990* (the TG Regulations) to support implementation of:

- the unique device identification (UDI) framework for medical devices;
- the mandatory reporting of adverse events involving medical devices by healthcare facilities; and
- more minor amendments to repeal a small number of fees for applications to add, vary or remove conditions on the entry of goods in the Australian Register of Therapeutic Goods (the Register).

The UDI framework will improve the identification and traceability of medical devices and effectiveness of responses to device safety issues, by providing for the establishment of the Australian Unique Device Identification Database and requiring the inclusion in the database of device identifiers (specially designed combinations of numbers, symbols and letters for identifying medical devices or their packaging) and related information, such as manufacturer name and any warnings or precautions about their use. The Amendment Regulations require such identifiers to be provided with a device and, in some instances, marked on the device itself. These reforms will enable the TGA to work with hospitals, health practitioners, patients, pharmacies and supply chain operators, such as distributors, to more quickly identify and address unsafe medical devices.

Schedule 2 also supports medical device safety, by identifying the kinds of medical devices for which adverse events involving such devices must be reported to the TGA under the mandatory reporting scheme for healthcare facilities, and related matters. These amendments will enable the TGA to better identify trends in medical device safety and to act more quickly to protect Australian patients from unsafe products.

Schedule 3 makes a small number of more minor amendments to address a concern that some of the new fees introduced by the *Therapeutic Goods Legislation (Fees and Other Measures) Regulations 2024*, which commenced on 1 January 2025, may not reflect the full range of circumstances or products in relation to which a request to impose, vary or remove a condition of entry in the Register may be made.

Human rights implications

The Amendment Regulations engage the right to health in Article 12 of the International Covenant on Economic, Social and Cultural Rights (the ICESCR) and the right to protection against arbitrary and unlawful interferences with privacy in Article 17 of the International Covenant on Civil and Political Rights (the ICCPR).

Right to health

Article 12 of the ICESCR promotes the right of all individuals to enjoy the highest attainable standard of physical and mental health and includes an obligation to take reasonable measures within available resources to progressively secure broader enjoyment of the right.

In *General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12) (2000),* the United Nations Committee on Economic, Social and Cultural Rights states that health is a 'fundamental human right indispensable for the exercise of other human rights', and that the right to health is not to be understood as the right to be healthy, but includes the right to a system of health protection which provides equal opportunity for people to enjoy the highest attainable level of health.

The Amendment Regulations take positive steps to promote the right to health by supporting the safety of Australian consumers in the use of medical devices in relation to amendments that provide for the establishment and maintenance of the database to significantly improve the traceability of medical devices in Australia, and the mandatory reporting of adverse events involving medical devices.

In particular, the Amendment Regulations promote the right to health by:

- supporting the improved traceability and monitoring of medical devices in Australia through the database and associated regulatory framework;
- enabling patients, consumers, and health professionals to access information more easily about UDI medical devices that they use, including if there is a device safety incident or recall related to that device;
- providing improved transparency and availability of device information, particularly for consumers and at the point of care, through the database and associated regulatory framework;

- enabling for faster responses to safety issues, and more rapid and targeted recalls of defective medical devices through faster and more accurate identification of devices, and effective management of medical device recalls through the mandatory reporting regulatory framework; and
- enabling for management of longer-term device failures that are more likely to have serious clinical impacts some years after the device implementation.

In supporting these reforms, the Amendment Regulations promote and address aspects of the right to health under Article 12 of the ICESCR that relate to recognising the right of everyone to enjoy the highest attainable standard of physical and mental health.

Right to protection against arbitrary and unlawful interferences with privacy

Article 17 of the ICCPR provides for the right of every person not to be subjected to arbitrary or unlawful interference with privacy. The prohibition on interference with privacy prohibits unlawful or arbitrary interferences with a person's privacy, family, home and correspondence. It also prohibits unlawful attacks on a person's reputation. Limitations on the right to privacy must be according to law and not arbitrary. Limitations must be reasonable and necessary in the circumstances, as well as proportionate to the objectives that the limitations seek to achieve.

The Amendment Regulations require healthcare facilities to report to the Secretary on adverse events involving reportable medical devices. The information required to be included in the report relates to the medical device, its manufacturer and the nature of the adverse event. The Amendment Regulations require the disclosure of personal information in certain circumstances, namely in the form of information about a person's health and medical treatment where they have used a reportable medical device.

The Amendment Regulations engage the right to protection against arbitrary and unlawful interferences with a person's privacy, family, home and correspondence. The Amendment Regulations only restrict the right to privacy in so far as authorising the disclosure of personal information that is reasonable, necessary and proportionate to improving traceability and monitoring of UDI medical devices in Australia, improving identification of trends in medical device safety and early detection of potential issues in medical devices, as well as protecting Australian patients from unsafe devices.

The Amendment Regulations prevent personal information being included in the database apart from information relating to the person in relation to whom the device is included in the Register, or their authorised representative, or an authorised representative of the manufacturer of a kind of medical device. Further, the Amendment Regulations provide that this personal information must not be included in the database unless the authorised representative consents to that inclusion.

As such, any personal information included in the database will be focused principally on the medical devices themselves and related information, rather than identifiable information relating to persons. The only personal information likely to be included in the database will be information that forms part of the name of a device sponsor or manufacturer, and such information is likely to already be in the public domain.

In relation to the mandatory reporting of adverse events involving medical devices by healthcare facilities framework, the Amendment Regulations are limited by the circumstances in which a report in relation to adverse events involving reportable medical devices will be required under section 41JM of the *Therapeutic Goods Amendment (2022 Measures No. 1) Act 2023.* The Amendment Regulations only authorise the disclosure of certain personal information where a medical device has resulted, or would result in, the death or serious deterioration in health of a person. That information is the time and/or the nature or description of the person's death or serious deterioration in the person's health, or intervention of the person in a healthcare facility, in limited circumstances outlined under section 41JM of the *Therapeutic Goods Amendment (2022 Measures No. 1) Act 2023*.

The TGA, as part of the Department, is an APP entity for the purposes of the *Privacy Act 1988* (the Privacy Act). Consequently, the collection or use of personal information must be consistent with the Privacy Act. The Department's privacy policy applies generally to this information.

As such, the collection or use of the information would not be an arbitrary or unlawful interference with a person's privacy under Article 17 of the ICCPR, as any personal information that was collected would be necessary in the particular circumstances.

Conclusion

The Amendment Regulations are compatible with human rights because they support the right to health in Article 12 of the ICESCR, engage the right to privacy in Article 17 of the ICESCR in a measured and proportionate way, as outlined above and otherwise do not raise any other human rights issues.

Mark Butler, Minister for Health and Aged Care