

## **EXPLANATORY STATEMENT**

### *Therapeutic Goods Act 1989*

#### *Therapeutic Goods Legislation Amendment (2023 Measures No. 1) Regulations 2023*

The Regulations support the introduction of a new low regulatory pathway for including export only biologicals in the Australian Register of Therapeutic Goods, and reduce regulatory burden for sponsors of clinical trials

The *Therapeutic Goods Act 1989* (the Act) establishes and maintains a national system of controls for the quality, safety, efficacy and timely availability of therapeutic goods used in, or exported from, Australia. Subsection 63(1) of the Act enables the Governor-General to make regulations, not inconsistent with the Act, prescribing matters 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 (2023 Measures No. 1) Regulations 2023* (the Regulations) amends the *Therapeutic Goods Regulations 1990* (the TG Regulations), principally to support the new low regulatory burden pathway for including export only biologicals (i.e. biologicals that are manufactured in, or imported into, Australia for export only) in the Australian Register of Therapeutic Goods (the Register) introduced by the *Therapeutic Goods Amendment (2022 Measures No. 1) Act 2023* (the Amendment Act). The Amendment Act received royal assent on 21 March 2023.

The Regulations also make a number of other amendments to the TG Regulations, and the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations), to:

- reduce regulatory burden, and improve flexibility, for clinical trial sponsors by allowing the Secretary to agree (in writing) to accept a late notification of information about a clinical trial after the trial has commenced. (The main pathway for the lawful supply of unapproved therapeutic goods in clinical trials requires a trial sponsor to notify the Secretary of the trial before it begins. Where this does not occur, the supply is unlawful and a new trial would be needed, a considerable and disproportionate impact on trial participants (who may be patients with serious conditions) and researchers;
- make a number of minor updates to the regulatory framework for Australian conformity assessment bodies (i.e. bodies authorised to assess compliance with conformity assessment principles in Australia) to improve consistency and clarity to better align the Australian requirements for such bodies with the requirements for notifiable bodies in the European Union (EU) (the Australian framework for such bodies is based on the EU framework for notifiable bodies), without introducing new regulatory steps for such bodies; and
- make a small number of minor amendments, to broaden the Departmental officers to whom the Secretary may delegate the Secretary's powers under certain provisions of the Act and remove redundant provisions.

Details of the Regulations are set out in the [Attachment](#).

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

The Regulations commence on the day after registration on the Federal Register of Legislation, except Part 1 of Schedule 1 which commences on the later of the day the instrument is registered, and immediately after the commencement of Schedule 2 to the Amendment Act. Schedule 2 to the Amendment Act will commence on 21 June 2023.

## **Consultation**

The TGA conducted a public consultation on the introduction of an export only biological pathway between 15 November 2021 and 22 December 2022. Four submissions were received, all supporting the creation of the new pathway.

The TGA consulted with the states and territories through the Clinical Trials Project Reference Group (CTPRG) on 14 December 2022 on the proposed amendments to improve the flexibility of the current clinical trials requirements. The CTPRG is an advisory group of senior officials from Commonwealth, State and Territory health departments. The CTPRG were supportive of the proposal to amend the regulations to include a discretion for the Secretary to agree to late notification of trials that are otherwise compliant.

No specific consultation was undertaken in relation to the proposed updates to the Australian conformity assessment bodies framework, as the amendments principally reflect minor corrections and do not introduce any new requirements.

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

**Details of the *Therapeutic Goods Legislation Amendment (2023 Measures No. 1) Regulations 2023***

**Section 1 – Name**

This section provides that the title of the Regulations is the *Therapeutic Goods Legislation Amendment (2023 Measures No. 1) Regulations 2023*.

**Section 2 – Commencement**

This section provides for the commencement of the Regulations on the day after registration on the Federal Register of Legislation, except Part 1 of Schedule 1 which commences on the later of the day the instrument is registered and immediately after the commencement of Schedule 2 to *Therapeutic Goods Amendment (Measures No. 1) Act 2023* (the Amendment Act).

**Section 3 – Authority**

This section provides that the 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 – Amendments

### Part 1—Export only biologicals

Schedule 2 to the Amendment Act introduced a new dedicated, low regulatory pathway to Part 3-2A of the Act for the inclusion of export only biologicals in the Australian Register of Therapeutic Goods (the Register).

The introduction of this new streamlined marking approval pathway for export only biologicals is designed to ensure consistency for all export only therapeutic goods (as export only categories already existed under the Act and related regulations for medicines and medical devices), and to provide an incentive for investment and innovation in the development of biologicals for export from Australia, including advanced treatments for serious diseases such as cancer. The amendments in this schedule make technical or consequential changes to the *Therapeutic Goods Regulations 1990* (the TG Regulations) to support the new pathway.

### ***Therapeutic Goods Regulations 1990***

#### **Items 1, 3, 4 and 5 – Regulation 2 (definition of Class 1 biological, Class 2 biological, Class 3 biological and Class 4 biological)**

These items amend the definitions of each class of biological in regulation 2 of the TG Regulations (Class 1 biological, Class 2 biological, Class 3 biological and Class 4 biological), to make it clear that ‘export only biologicals’ is a separate class of biological to those existing classes, and that the existing classes do not include export only biologicals. The purpose of this amendment is to exclude export only biologicals from the existing classes of biological, even if they would otherwise meet such a definition. For example, if a biological meets the definition of a Class 2 biological but is intended by the person in relation to whom the biological is included in the Register to be for export only, it would be an export only biological.

#### **Item 2 – Regulation 2 (note to the definition of Class 1 biological)**

This item repeals the note to the definition of Class 1 biological in regulation 2 of the TG Regulations which states that “At the time these Regulations commenced, there were no Class 1 biologicals”. This note is redundant as there are now several Class 1 biologicals included in the Register.

#### **Items 6-8 – Regulation 2 (definition of *TGA notifications process guidance document*, and the note to the definition of *TGA notifications process guidance document*)**

This item amends the definition of *TGA notifications process guidance document* in regulation 2 of the TG Regulations to refer to version 4.0 of the document titled “*Notifications process-requests to vary biologicals and registered medicines where quality, safety and efficacy are not affected*”.

This item also amends the note to this definition to reflect that the TGA notification process guidance document can in 2023 be viewed on the TGA website.

The amendments to this definition incorporate by reference the document “*Notifications process-requests to vary biologicals and registered medicines where quality, safety and efficacy are not affected*” (Version 4.0). In accordance with paragraph 14(1)(b) of the

*Legislation Act 2003*, this document has been incorporated as in force on 21 June 2023. This document is available for free from the TGA's website at [www.tga.gov.au](http://www.tga.gov.au).

**Item 9 – At the end of Part 1**

This item amends the TG Regulations to introduce new regulation 3C. The new provision groups the prescribing of all of the classes of biologicals under one provision, and identifies the new class of export only biologicals.

**Item 10 – Subregulation 10AAD(2) (at the end of the table)**

Subsection 9D(3AC) of the Act provides that where a person in relation to whom a biological is included in the Register requests a variation to the entry in the Register that relates to the biological and the variation is of a kind specified in the regulations, and where any conditions specified in the regulations are satisfied, the Secretary must vary the entry in accordance with the request. Regulation 10AAD of the TG Regulations sets out kinds of variations and conditions for the purposes of paragraphs 9D(3AC)(b) and (c) of the Act.

This item introduces new item 13 to the table in subregulation 10AAD(2) to introduce such a variation in relation to export only biologicals. The variation concerned involves a change to the information included in the entry in the Register for the export only biological, subject to the following conditions:

- the change must not result in a separate and distinct biological; and
- if the change is to add a new manufacturer, the Secretary has certified, under section 32EB of the Act, that the manufacturing and quality control procedures used in the steps of the manufacture of the export only biological undertaken by the manufacturer are acceptable.

**Item 11 – At the end of subregulation 11A(1)**

Section 32AB of the Act provides for the regulations to prescribe circumstances in which a biological included in a specified class of biologicals is separate and distinct from other biologicals. Regulation 11A of the TG Regulations sets out the characteristics for this purpose.

This item amends subregulation 11A(1) to introduce new paragraph (c) to specify the characteristics that distinguish an export only biological from other biologicals, for the purposes of section 32AB. The effect of this amendment is that an export only biological will be separate and distinct from other biologicals if the export only biological differs in respect of any of the following:

- active ingredient;
- dosage form;
- principal manufacturer.

**Item 12 – At the end of subregulation 16V(1)**

Regulation 16V of the TG Regulations provides for the making of a biologicals (priority applicant) determination in relation to a biological, other than a Class 1 biological. The priority applicant pathway provides a mechanism for critical, life-saving biologicals to be assessed within a shorter timeframe than the standard assessment pathway so that they may be made available to Australian patients quickly, if approved. This pathway is not designed for Class 1 biologicals currently, and is also not intended for export only biologicals as these are exported rather than being supplied in the Australian market.

This item amends subregulation 16V(1) to provide that export only biologicals are excluded from being the subject of an application for a biological (priority applicant) determination.

**Item 13 – Part 2 of Schedule 9A (after table item 2)**

Paragraph 32DCA(2)(c) of the Act (as introduced by the Amendment Act) provides for the regulations to prescribe the fee for an application for the inclusion of an export only biological in the Register.

This item introduces new item 2AA to the table in Part 2 of Schedule 9A to the TG Regulations to prescribe the application fee for an application to include an export only biological in the Register, in the amount of \$1,231.

## Part 2—Clinical trials

Paragraph 41HA(1)(b) of the Act provides that the regulations may exempt specified kinds of medical devices from the operation of Division 3 of Part 4-11 of the Act, with the effect of enabling the regulations to exempt certain specified kinds of medical devices from the requirement to be included in the Register before being able to be lawfully imported into, supplied in or exported from, Australia. Subsection 41HA(2) provides that such an exemption may be subject to conditions that are prescribed in the regulations. Section 18A sets out equivalent arrangements for medicines, and section 32CA sets out equivalent arrangements for biologicals.

Item 2.3 of the table in Part 2 of Schedule 4 to the MD Regulations exempts kinds of medical devices that are used solely in clinical trials from the requirements to be included in the Register, subject to a number of specified conditions. Currently, the condition in paragraph (a) of column 3 requires trial sponsors to notify the Secretary, before starting to use specified kinds of devices, that the sponsor intends to sponsor a clinical trial. Item 3 of Schedule 5A to the TG Regulations sets out an equivalent requirement applying to the exemption of medicines and biologicals that are used in clinical trials.

Together, these provisions form the basis of the TGA's Clinical Trials Notification (CTN) scheme, which is the principal pathway relied upon by persons seeking to supply unapproved therapeutic goods in a clinical trial in Australia.

It has been identified that in some instances trial sponsors have not submitted the required notification before the use of unapproved therapeutic goods in the trial has commenced. Failure to provide this notification before using the goods means that the condition in paragraph (a) of the conditions of each CTN scheme exemption (item 3 of Schedule 5A to the TG Regulations, and item 2.3 in Part 2 of Schedule 4 to the MD Regulations) is not able to be satisfied, with the effect that the relevant exemption does not apply to the trial and the supply of the goods in the trial is unlawful.

As there is currently no mechanism to remedy this with the scope of the exemptions, the only option available is termination of the trial. This outcome is disproportionate and may have significant impacts on trial operators, research and product development timelines, sponsors and patients, who may in some instances include patients with serious illnesses and conditions.

The purpose of the amendments in this Part is to amend the TG Regulations and MD Regulations to improve flexibility in this area by providing a mechanism to enable the Secretary to agree to a late notification. This will preserve the continuation of the clinical trial, avoiding the adverse consequences that may be caused by termination of the trial.

### ***Therapeutic Goods (Medical Devices) Regulations 2002***

#### **Item 14 – Paragraph 7.4(1)(a)**

This item makes a minor editorial amendment to paragraph 7.4(1)(a) of the MD Regulations to omit the words “enter the” and substitute “enter a” to better reflect that there may be more than one trial site for a particular clinical trial.

**Items 15 and 16 – Subregulation 10.7 (1) (at the end of the of the definition of *initial decision* and after subregulation 10.7(1))**

Item 15 makes a minor editorial amendment to introduce a note to the definition of *initial decision* to support the introduction of new subregulation 10.7(1A).

Item 16 introduces new subregulation 10.7(1A) with the effect that a decision of the Secretary to refuse to agree to a late notification about the use of the kinds of medical device in a trial, or a later notification about a trial site, is an ‘initial decision’ and is therefore subject to the review and appeal rights provided in regulation 10.7 to the MD Regulations.

**Item 17 – Part 2 of Schedule 4 (table item 2.3, column headed “Kinds of medical devices”)**

This item amends the column headed “Kinds of medical devices” of item 2.3 in the table in Part 2 of Schedule 4 to the MD Regulations to add in the words “in a clinical trial” to accommodate other amendments made by this Part and align with the language used in this item that refers to clinical trials.

**Item 18 – Part 2 of Schedule 4 (table item 2.3, column headed “Conditions”, paragraph (a))**

This item replaces paragraph (a) in the column headed “Conditions” in item 2.3 in the table in Part 2 of Schedule 4 to the MD Regulations to provide that the sponsor of a clinical trial must notify the Secretary about a clinical trial, and the kinds of medical devices covered by the trial, either:

- before the kinds of device begin to be used in the trial; or
- where the sponsor nominates an alternative period and seeks the Secretary’s agreement to a late notification—the end of the agreed period for the late notification.

This amendment has the effect of enabling the Secretary to agree (in writing) to accept a notification by the sponsor about a clinical trial or the devices to be used in the trial, after the use of the devices in the clinical trial has commenced. The amendment is intended to allow for the late notification of information in appropriate cases without resulting in the termination of the trial.

**Item 19 – Part 2 of Schedule 4 (at the end of the cell at table item 2.3, column headed “Conditions”)**

This item introduces new paragraph (h) in the column headed “Conditions” in item 2.3 in the table in Part 2 of Schedule 4 to the MD Regulations to provide that the sponsor of a clinical trial must notify the Secretary about any trial site not covered by a notification referred to in paragraph (a) (as amended above) either:

- before the kinds of medical device begin to be used in the trial; or
- where the nominates an alternative period and seeks the Secretary agrees to that period—the end of that agreed period.

This amendment makes it clear that where an additional trial site is added for a medical device CTN clinical trial and the site has not already been notified to the Secretary, it must be so notified, either before the trial commences or within an alternative period as agreed by the Secretary.

## ***Therapeutic Goods Regulations 1990***

### **Item 20 – Subregulation 12AC(1)**

This item makes a minor amendment to subregulation 12AC(1) of the TG Regulations to include a reference to a clinical trial mentioned in column 2 of item 3 of the table in Schedule 5A. This amendment makes it clear that the powers of an authorised officer under that provision may be exercised in relation to any clinical trial, including where the trial did not comply with the conditions mentioned in column 3. The intention of this amendment is to ensure that authorised officers can investigate all clinical trials, including where a trial may be non-compliant with applicable conditions.

### **Item 21 – Paragraph 12AC(1)(a)**

This item makes a minor editorial amendment to paragraph 12AC(1)(a) of the TG Regulations to omit the words “enter the” and substitute “enter a” to better reflect that there may be more than one trial site for a particular clinical trial.

### **Items 22 to 24 – Subregulation 48(1) (definition of *eligible person* and note to the definition of *initial decision*) and after subregulation 48(1AA)**

These items amend regulation 48 of the TG Regulations to make it clear that a decision of the Secretary to refuse to agree to a late notification about the use of the goods, or a later notification about a trial site, is subject to review and appeal rights provided in regulation 48 of the TG Regulations.

### **Item 25 – Schedule 5A (table item 3, column 2)**

This item amends column 2 of item 3 in the table in Schedule 5A to the TG Regulations to replace the word “used” with “to be used in a clinical trial” to accommodate the amendments made by items in this Part and align with the exemption for medical devices (in item 2.3 in the table in Part 2 of Schedule 4 to the MD Regulations).

### **Item 26 – Schedule 5A (table item 3, column 3, paragraph (a))**

This item replaces paragraph (a) in column 3 of item 3 in the table in Schedule 5A to the TG Regulations to provide that the sponsor of a clinical trial must notify the Secretary about a clinical trial and the therapeutic goods covered by the trial either:

- before the goods begin to be used in the trial; or
- where the sponsor has sought the Secretary’s agreement to a late notification—the end of the agreed period for the late notification.

This amendment has the effect of enabling the Secretary to agree (in writing) to accept a notification by the sponsor about a clinical trial or the goods to be used in the trial, after the use of the goods in the clinical trial has commenced. The amendment is intended to allow for the late notification of information in appropriate cases without resulting in the termination of the trial.

### **Item 27 – Schedule 5A (table item 3, column 3, paragraph (b))**

This item amends paragraph (b) in column 3 of item 3 in the table in Schedule 5A to the TG Regulations to make it clear that a notification made under paragraph (a) (as amended above) must be accompanied by the fee referred to in paragraph (a) of column 2 of item 14 in clause 3 of Schedule 9 or paragraph (a) of the column headed “Matter” in item 17 of the table in Part 2 of Schedule 9A.

**Item 28 – Schedule 5A (table item 3, column 3, after paragraph (h))**

This item introduces new paragraphs (ha) and (hb) in column 3 of item 3 in the table in Schedule 5A to the TG Regulations.

New paragraph (ha) provides that the sponsor of a clinical trial must notify the Secretary about any trial site not covered by a notification referred to in paragraph (a) (as amended above):

- before the goods begin to be used in the trial; or
- where the sponsor has sought the Secretary’s agreement to a late notification—the end of the agreed period for the late notification.

New paragraph (hb) provides that a notification made under new paragraph (ha) must be accompanied by the fee referred to in paragraph (b) of column 2 of item 14 in clause 3 of Schedule 9 or paragraph (b) of the column headed “Matter” in item 17 of the table in Part 2 of Schedule 9A.

These amendments make it clear that where an additional trial site is added for a medicines or biologicals CTN clinical trial and the site has not already been notified to the Secretary, it must be so notified, either before the trial commences or within an alternative period as agreed by the Secretary.

### Part 3—Delegations

Section 41HD of the Act enables the Secretary to approve the importation or supply of unapproved medical devices, where alternative kinds of medical devices included in the Register that could act as a substitute are unavailable or are in short supply. Similarly, sections 19A and 32CO of the Act enable the Secretary to approve the importation or supply of unapproved medicines and biologicals, respectively, where alternative registered goods that could act as a substitute are unavailable, in short supply, or in the case of medicines, are no longer in the Register.

Under subsections 57(8) and (9) of the Act, the powers of the Secretary under sections 19A, 32CO and 41HD of the Act may only be delegated to a person who holds, occupies or performs the duties of a position in the Department prescribed by the regulations. Currently, regulation 10.6A of the MD Regulations and subregulation 46A(2) of the TG Regulations prescribes the following positions for the purposes of subsections 57(8) and (9) of the Act:

- First Assistant Secretary, Medicines Regulation Division;
- First Assistant Secretary, Medical Devices and Product Quality Division;
- Chief Medical Adviser, Health Products Regulation Group;
- each position classified as Medical Officer Class 5, Health Products Regulation Group.

These prescribed persons are fairly limited and the volume of approvals granted means that it is overly burdensome on such senior officials to be granting all approvals. It is intended that delegations be able to be made to other senior positions within the Department (Senior Executive positions, Executive Level positions and Medical Officer positions) to improve efficiency in processing, ensure there are a sufficient number of delegates who can make such decisions when a large number of applications are received, and ensure that Departmental officers who are involved in making arrangements for alternative supply of therapeutic goods that are unavailable or in short supply are able to hold the delegation to make approval decisions where appropriate.

The proposal to delegate such powers to these additional positions is considered appropriate as the granting of such approvals in a timely manner is essential to appropriately manage therapeutic goods shortages, to ensure that the Australian public can continue to access critical therapeutic goods (for example, antibiotics). Medicine shortages are an increasing problem with global impact, not just in Australia. If the TGA is not able to move quickly, the consequence may be that it may not be possible to secure supplies of important medicines for Australian patients, with potentially significant consequences for patient health.

#### ***Therapeutic Goods (Medical Devices) Regulations 2002***

##### **Item 29 – Paragraphs 10.6A(a) to (d)**

This item replaces paragraphs (a) to (d) of regulation 10.6A of the MD Regulations with new paragraphs (a) to (c), to expand the persons who may be delegated the Secretary's power under section 41HD of the Act. This better reflects the TGA's intended work practices, and ensure there are a sufficient number of delegates who are able to exercise the Secretary's powers under those sections.

New paragraphs 10.6A(a) to (c) provides that for subsection 57(9) of the Act, the following positions are prescribed:

- an SES Band 1, 2 or 3 position;
- each position classified as a Medical Officer Class 3, 4, 5 or 6;
- an Executive Level 1 or 2 position.

### ***Therapeutic Goods Regulations 1990***

#### **Item 30 – Subregulation 46A(2)**

This item replaces subregulation 46A(2) of the TG Regulations with a new subregulation 46A(2) to expand the persons who may be delegated the Secretary’s power under sections 19A and 32CO of the Act. This better reflects the TGA’s intended work practices, and ensure that there are a sufficient number of delegates who are able to exercise the Secretary’s powers under those sections.

New subregulation 46A(2) provides that for subsection 57(8) of the Act, the following positions are prescribed:

- an SES Band 1, 2 or 3 position;
- each position classified as a Medical Officer Class 3, 4, 5 or 6;
- an Executive Level 1 or 2 position.

## Part 4—Australian conformity assessment bodies

Section 41EWA of the Act provides that the regulations may make provision for and in relation to empowering the Secretary to make conformity assessment body determinations, with the effect that an Australian corporation that is the subject of such a determination would be able to assess the suitability of, and issue certificates relating to, the manufacturing of medical devices, similar to the role that notified bodies undertake in this regard in the European Union.

Part 4A of the MD Regulations sets out the Australian conformity assessment body (CAB) scheme, and Schedule 3AA to the MD Regulations sets out the main criteria for applying for, and maintaining, a conformity assessment body determination.

A small number of errors or omissions have been identified in the provisions supporting the CAB scheme, principally in Schedule 3AA to the MD Regulations. The amendments in this Part make the necessary corrections, without changing the application of the existing provisions.

A number of amendments to Schedule 3AA incorporate by reference the following documents:

- *Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices* (the EU medical devices regulations); and
- *Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro medical devices* (the EU IVD regulations), together, the EU regulations.

These documents have been incorporated as in force from time to time in accordance with section 63(4) of the Act (which provides a contrary intention to the application of section 14 of the *Legislation Act 2003*). These documents are freely available from EUR-Lex at <https://eur-lex.europa.eu/>.

### ***Therapeutic Goods (Medical Devices) Regulations 2002***

#### **Item 31 – Subclause 3(2) of Schedule 3AA (table items 1 to 3)**

This item replaces items 1 to 3 of the table in subclause 3(2) of Schedule 3AA to the MD Regulations to update the terms mentioned in the EU regulations that are taken to be modified for the purposes of subclause 2(1). In particular, this item:

- introduces new paragraph (c) in item 1 with the effect that a reference to the term “Union and national” in the EU regulations is taken to be a reference to “Australian”;
- introduces new item 1A with the effect that a reference to the terms “a Member State”, or “the Member State” or “that Member State” in the EU regulations is taken to be a reference to “Australia”;
- replaces paragraph (b) of item 2 with a new paragraph (b) with the effect that a reference to “competent authorities” in the EU regulations is taken to be a reference to the Secretary; and
- introduces a new item 3A with the effect that a reference to the term “notified bodies” in the EU regulations is taken to be a reference to “Australian conformity assessment bodies”.

**Item 32 – Subclause 3(2) of Schedule 3AA (at the end of the cell at table item 5, column 1)**

This item introduces new paragraph (c) in item 5 of the table in subclause 3(2) of Schedule 3AA to the MD Regulations with the effect that a reference to the term “this Annex” in the EU regulations is taken to be a reference to the term “these Regulations”.

**Item 33 – Subclause 3(2) of Schedule 3AA (table item 7)**

This item replace item 7 of the table in subclause 3(2) of Schedule 3AA to the MD Regulations with a new item 7, with the effect that references to “general safety and performance requirements set out in Annex 1” (paragraph (a)), “requirements in Annex 1” (paragraph (b)), and “requirements laid down in Annex 1” (paragraph (c)) are taken to be a reference to the term “essential principles”.

**Item 34 – Subclause 3(2) of Schedule 3AA (table item 8, column 1, paragraph (a))**

This item amends column 1 of item 8 of the table in subclause 3(2) of Schedule 3AA to the MD Regulations to make an editorial amendment to refer to the plural “annexes”.

**Items 35 and 37 – Subclause 3(2) of Schedule 3AA (table item 10 and table item 12)**

These items repeal items 10 and 12 of the table in subclause 3(2) of Schedule 3AA to the MD Regulations.

**Item 36 – Subclause 3(2) of Schedule 3AA (table item 11, column 2)**

This item makes a minor editorial amendment to remove the word “the” from column 2 of item 11 of the table in subclause 3(2) of Schedule 3AA to the MD Regulations.

**Item 38 – Subclause 3(2) of Schedule 3AA (cell at table item 15, column 1)**

This item replaces column 1 of item 15 in the table in subclause 3(2) of Schedule 3AA to the MD Regulations with the effect that a reference to the terms “post-market surveillance” or “post-market surveillance plan” in the EU regulations is taken to be a reference to the term “post-marketing requirements mentioned in Schedule 3 to these Regulations”.

**Item 39 – Subclause 3(2) of Schedule 3AA (at the end of the table)**

This item introduces new table item 18 in subclause 3(2) of Schedule 3AA to the MD Regulations to provide that a reference to the term “shall” in the EU Regulations is taken to be a reference to the term “must”.

**Item 40 – At the end of subclause 3(3) of Schedule 3AA**

This item amends subclause 3(3) of Schedule 3AA to the MD Regulations to include an example to clarify that item 4 of the table in subclause 3(2) does not apply to the reference to “authorised representative” in Section 4.3 of each EU regulation (subparagraph 3(6)(c)(i) of the MD Regulations refers).

**Item 41– Subparagraph 3(6)(a)(i) of Schedule 3AA**

This item amends subparagraph 3(6)(a)(i) of Schedule 3AA to the MD Regulations with the effect that Sections 1.6.1, 3.2.1 and 4.5.6 of each EU regulation are no longer disregarded.

**Item 42 – Subparagraphs 3(6)(a)(iii) to (v) of Schedule 3AA**

This item repeals subparagraphs 3(6)(iv) and (v), and replace subparagraph 3(6)(iii) of Schedule 3AA of the MD Regulations with the effect that the words “or previously applicable law within a notified body” in Section 3.3.2 in each EU regulation are to be discarded.

**Item 43 – Subparagraph 3(6)(a) (viii) of Schedule 3AA**

This item repeals subparagraph 3(6)(a) (viii) of Schedule 3AA to the MD Regulations.

**Item 44 – Paragraphs 3(6)(b) and (c) of Schedule 3AA**

This item replaces paragraphs 3(6)(b) and (c) and introduce new paragraph 3(6)(ba) in Schedule 3AA to the MD Regulations.

New paragraph 3(6)(b) has the effect that in Section 3.1.1 of each EU regulation, the words “performance and safety of devices” are replaced with the words “compliance with the essential principles” (subparagraph 3(6)(b)(i)) and the words “those set out in Annex I” are replaced with the words “the essential principles” (subparagraph 3(6)(b)(ii)).

New paragraph 3(6)(ba) has the effect that in Section 3.3.1 of each EU regulation, the words “the authority responsible for notified bodies” are replaced with the words “the Secretary”.

New paragraph 3(6)(c) has the effect that in section 4.3 of each EU regulation:

- a reference to an authorised representative is taken to be a reference to an applicant authorised by the manufacturer (subparagraph 3(6)(c)(i)); and
- a reference to the corresponding Annex is taken to be a reference to the corresponding part of Schedule 3 to these Regulations (subparagraph 3(6)(c)(ii)); and
- the word “approval” is replaced with the word “assessment” (subparagraph 3(6)(c)(iii)).

**Item 45 – After paragraph 3(6)(d) of Schedule 3AA**

This item introduces new subparagraph 3(6)(da) in Schedule 3AA to the MD Regulations with the effect that in Section 4.5.2 of each EU regulation, the words “post-market surveillance information” are replaced with the words “information from post-marketing requirements mentioned in Schedule 3 to these Regulations”.

**Item 46 – After paragraph 3(6)(e) of Schedule 3AA**

This item introduces new subparagraph 3(6)(ea) in Schedule 3AA to the MD Regulations with the effect that in Section 4.6 of each EU regulation, the words “personnel in designating authorities” are replaced with the words “the Secretary”.

**Item 47 – Subparagraph 3(6)(f)(i) of Schedule 3AA**

This item repeals subparagraph 3(6)(f)(i) of Schedule 3AA to the MD Regulations.

**Item 48 – Subclauses 5(3) and (4) of Schedule 3AA**

This item replaces subclauses 5(3) and (4) of Schedule 3AA to the MD Regulations with a new subclause 5(3), which provides for the modification of the EU medical devices regulations. In particular:

- new paragraph 5(3)(a) provides that a number of provisions in the EU medical device regulations are to be disregarded;

- new paragraph 5(3)(b) provides that in Section 1.6.1 of the EU medical devices regulations, the words “notified body coordination group referred to in Article 49” are replaced with the word “Secretary”;
- new paragraph 5(3)(c) provides that in Section 3.2.2 of the EU medical devices regulations, the words “Article 42(3)” are replaced with the words “Annex 1 of Commission Implementing Regulation (EU) 2017/2185 of 23 November 2017 on the lists of codes and corresponding types of devices for the purpose of specifying the scope of the designation as notified bodies in the field of medical devices under Regulation (EU) 2017/745 of the European Parliament and of the Council and in vitro diagnostic medical devices under Regulation (EU) 2017/746 of the European Parliament and of the Council (Commission Implementing EU) 2017/2185”;
- new paragraph 5(3)(d) provides that in point (a) of Section 4.5.3 of the EU medical devices regulations, the words “Part B of Annex XI” are replaced with the words “Part 3 of Schedule 3 to these Regulations”;
- new paragraph 5(3)(e) provides that in point (b) of section 4.5.3 of the EU medical devices regulations, the words “the EU” are replaced with the words “a relevant”;
- new paragraph 5(3)(f) provides that in Section 4.5.5 of the EU medical device regulations, the words “Annex XIV (wherever occurring) are replaced with the words “Part 8 of Schedule 3 to these Regulations”; and
- new paragraph 5(3)(g) provides that in Section 4.5.6 of the EU medical devices regulations:
  - the words “sufficient expertise and facilities for the procedures referred to in Sections 5 and 6 of Annex IX, Section 6 of Annex X and Section 16 of Annex XI, for which they are designated” are replaced with the words “allowing for external expert opinions to be sought when required to ensure an adequate assessment of compliance with these Regulations; and
  - the words “that Regulation” are replaced with the words “these Regulations”;
- new paragraph 5(3)(h) provides that in Section 4.10 of the EU medical device regulations the words “observe the manufacturer’s and competent authority’s activities and the results of the manufacturer’s investigation” are replaced with the words “observe the manufacturer’s activities and the results of the manufacturer’s investigation, and be aware of information relating to the Secretary’s vigilance and monitoring activities that is available on the TGA’s website”.

#### **Item 49 – Subclause 6(3) of Schedule 3AA**

This item replaces subclause 6(3) of Schedule 3AA to the MD Regulations with a new subclause 6(3), which provides for the modification of the EU IVD regulations. In particular:

- new paragraph 6(3)(a) provides that a number of provisions in the EU IVD regulations are to be disregarded;
- new paragraph 6(3)(b) provides that in Section 1.6.1 of the EU IVD regulations. the words “notified body coordination group referred to in Article 49 of Regulation (EU) 2017/745” are replace with the word “Secretary”;
- new paragraph 6(3)(c) provides that in Section 3.2.2 of the EU IVD regulations:
  - the words “self and near patient testing” are replaced with the words “self-testing and point of care testing”; and
  - the words “Article 38(3)” are replaced with the words “Annex II of Commission Implementing Regulation (EU) 2017/2185 of 23 November 2017 on the list of code and corresponding types of devices for the purposes of specifying the scope of the designation a notified bodies in the field of medical

devices under Regulation (EU) 2017/745 of the European Parliament and of the Council and in vitro medical devices under Regulation (EU) 2017/746 of the European Parliament and of the Council (Commission Implementing (EU) 2017/2185”;

- new paragraph 6(3)(d) provides that in Section 4.5.5 of the EU IVD regulations, the words “sufficient expertise and facilities for the procedures referred to in Section 5 of Annex IX, for which that are designated” are replaced with the words “allowing for external expert opinions to be sought when required to ensure adequate assessment of compliance with the essential principles and these Regulations”;
- new paragraph 6(3)(e) provides that in Section 4.10 of the EU IVD regulations the words “observe the manufacturer’s and competent authorities’ activities and the results of the manufacturer’s investigation” are replaced with the words “observe the manufacturer’s activities and the results of the manufacturer’s investigation, and be aware of information relating to the Secretary’s vigilance and monitoring activities that is available on the TGA’s website”.
- new paragraph 6(3)(f) provides that a reference to a class B device is taken to be a reference to a Class 2 IVD medical device;
- new paragraph 6(3)(g) provides that a reference to a class C device is taken to be a reference to a Class 3 IVD medical device.

## Part 5—Minor amendments

### ***Therapeutic Goods (Medical Devices) Regulations 2002***

#### **Item 50 – Regulation 5.6**

This item repeals regulation 5.6 of the MD Regulations, as this provision is now redundant.

Subsection 41FN(3) of the Act provides that it is a condition of inclusion in the Register that the person in relation to whom the kinds of medical device is included in the Register will have available certain information or have procedures in place (including a written agreement) in which they can obtain that information from the manufacturer within the period prescribed by the regulations. Currently, regulation 5.6 of the MD Regulations prescribes a 20-working day period for the purposes of paragraphs 41FN(3)(a)(ii) and (b)(iii).

Items 24-26 of Schedule 12 to the Amendment Act made a number of minor amendments to subsection 41FN(3) of the Act, to clarify the provisions relating to these conditions, including, in particular, to expressly prescribe a period of 20 working days as the period of time in which a such a person must be able to obtain information from the manufacturer. As this timeframe is now provided for expressly in the Act, regulation 5.6 is redundant and can be repealed.

#### **Item 51 – Subregulation 10.7(9) (note)**

This item amends the note to subregulation 10.7(9) of the MD Regulations to remove an outdated reference to the location of a legislative instrument made under the *Administrative Appeals Tribunal Act 1975*.

### ***Therapeutic Goods Regulations 1990***

#### **Item 52 – Subregulation 12B(1B) (table item 46)**

This item repeals table item 46 (lorazepam) from the table in subregulation 12B(1B) of the TG Regulations as medicines containing the active ingredient lorazepam have now been included in the Register, meaning they are available for commercial supply and do not require access through the Authorised Prescriber Scheme.

## Part 6—Application provisions

### ***Therapeutic Goods (Medical Devices) Regulations 2002***

#### **Item 53 – In the appropriate position in Part 11**

This item amends the MD Regulations to introduce new Division 11.17 to set out the application provision relevant to the amendments made by Part 2 of Schedule 1 to the Regulations.

New regulation 11.71 provides that the amendments to item 2.3 in the table in Part 2 of Schedule 4 to the MD Regulations made by items 17 to 19 above apply in relation to a clinical trial where the kinds of medical device begin to be used in the trial on or after the commencement of those amendments, whether the clinical trial began before, on or after that commencement.

### ***Therapeutic Goods Regulations 1990***

#### **Item 54 –In the appropriate position in Part 9**

This item amends the TG Regulations to introduce new Division 21 to set out the application provision relevant to the amendments made by Part 2 of Schedule 1 to the Regulations.

New regulation 90 provides that the amendments to item 3 in the table in Schedule 5A to the TG Regulations made by items 25 to 28 above apply in relation to a clinical trial where goods begin to be used in the trial on or after the commencement of those amendments, whether the clinical trial began before, on or after that commencement.

## Statement of Compatibility with Human Rights

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

### **Therapeutic Goods Legislation Amendment (2023 Measures No. 1) Regulations 2023**

The *Therapeutic Goods Legislation Amendment (2023 Measures No. 1) Regulations 2023* (the Regulations) are 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 Regulations are made under subsection 63(1) of the *Therapeutic Goods Act 1989* (the Act).

The purpose of the Regulations is to amend the *Therapeutic Goods Regulations 1990* (the TG Regulations), principally to support the new low regulatory burden pathway for including export only biologicals (i.e. biologicals that are manufactured in, or imported into, Australia for export only) in the Australian Register of Therapeutic Goods (the Register) introduced by the *Therapeutic Goods Amendment (2022 Measures No. 1) Act 2023* (the Amendment Act). The Amendment Act received royal assent on 21 March 2023.

The Regulations also make a number of other amendments to the TG Regulations, and the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations), to:

- reduce regulatory burden, and improve flexibility, for clinical trial sponsors by allowing the Secretary to agree (in writing) to accept a late notification of information about a clinical trial after the trial has commenced. (The main pathway for the lawful supply of unapproved therapeutic goods in clinical trials requires a trial sponsor to notify the Secretary of the trial before it begins. Where this does not occur the supply is unlawful and a new trial would be needed, a considerable and disproportionate impact on trial participants (who may be patients with serious conditions) and researchers);
- make a number of minor updates to the regulatory framework for Australian conformity assessment bodies (i.e. bodies authorised to assess compliance with conformity assessment principles in Australia) to improve consistency and clarity to better align the Australian requirements for such bodies with the requirements for notifiable bodies in the European Union (EU) (the Australian framework for such bodies is based on the EU framework for notifiable bodies), without introducing new regulatory steps for such bodies; and
- make a small number of minor amendments, to broaden the Departmental officers to whom the Secretary may delegate the Secretary's powers under certain provisions of the Act and remove redundant provisions.

#### **Human rights implications**

The Regulations engage the right to health in Article 12 of the International Covenant on Economic, Social and Cultural Rights (the ICESCR). Article 12 of the ICESCR promotes the right of all individuals to enjoy the highest attainable standards of physical and mental health.

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 Regulations take positive steps to support the right to health in particular by expanding the positions to which the Secretary’s powers under the Act to approve the importation or supply of unapproved therapeutic goods may be delegated. The granting of such approvals is a critical tool in managing therapeutic goods shortages in Australia. This measure enables the granting of such approvals in a timely manner, to ensure that the Australian public can continue to access critical therapeutic goods (for example, antibiotics). Medicine shortages are an increasing problem with global impact, not just in Australia. This means that at a practical level, Australia is often competing at an international level for available supplies of medicines that could fill a gap in supply. If the TGA is not able to move quickly to secure supplies for import and supply in Australia, the consequence may be that it would not be possible to obtain medicines for the Australian’s who need to take them, with significant consequences for patient health.

Additionally, the Regulations further support the right to health by:

- facilitating the continuation of important clinical trials, by allowing the Secretary to agree to later notification of information about the trial, to support access to critical new treatments for Australians and ensure that patients involved in clinical trials can continue to access treatments; and
- clarifying the regulatory requirements in relation the Australian conformity assessment body scheme, as better alignment with the EU requirements encourages supply of medical devices in Australia (so sponsors do not have to meet two separate sets of regulatory requirements).

### **Conclusion**

The Regulations are compatible with human rights because they maintain and support the right to health in Article 12 of the ICESCR as outlined above, and do not raise any other human rights issues.

**Mark Butler, Minister for Health and Aged Care**