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

I, General the Honourable David Hurley AC DSC (Retd), Governor-General of the Commonwealth of Australia, acting with the advice of the Federal Executive Council, make the following regulations.

Dated 8 June 2023

David Hurley
Governor-General

By His Excellency's Command

Mark Butler
Minister for Health and Aged Care

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1 Name

This instrument is the *Therapeutic Goods Legislation Amendment (2023 Measures No. 1) Regulations 2023*.

2 Commencement

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

Commencement information

Column 1	Column 2	Column 3
Provisions	**Commencement**	**Date/Details**
1. Sections 1 to 4 and anything in this instrument not elsewhere covered by this table	The day after this instrument is registered.	14 June 2023
2. Schedule 1, Part 1	The later of: (a) the start of the day after this instrument is registered; and (b) immediately after the commencement of Schedule 2 to the *Therapeutic Goods Amendment (2022 Measures No. 1) Act 2023*.	21 June 2023
3. Schedule 1, Parts 2 to 6	The day after this instrument is registered.	14 June 2023

Note: This table relates only to the provisions of this instrument as originally made.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

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

3 Authority

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

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

Part 1—Export only biologicals

Therapeutic Goods Regulations 1990

1 Regulation 2 (definition of *Class 1 biological*)

After "a biological", insert "(other than an export only biological)".

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

Repeal the note.

3 Regulation 2 (definition of *Class 2 biological*)

After "a biological", insert "(other than an export only biological)".

4 Regulation 2 (definition of *Class 3 biological*)

After "a biological", insert "(other than an export only biological)".

5 Regulation 2 (definition of *Class 4 biological*)

After "a biological", insert "(other than an export only biological)".

6 Regulation 2 (definition of *TGA notifications process guidance document*)

Omit "Version 3.0", substitute "Version 4.0".

7 Regulation 2 (definition of *TGA notifications process guidance document*)

Omit "1 July 2018", substitute "21 June 2023".

8 Regulation 2 (note to the definition of *TGA notifications process guidance document*)

Omit "2018", substitute "2023".

9 At the end of Part 1

Add:

3C Classes of biologicals

For the purposes of section 32AA of the Act, the prescribed classes of biologicals are the following:

(a) Class 1 biological;
(b) Class 2 biological;
(c) Class 3 biological;
(d) Class 4 biological;
(e) export only biological.

10 Subregulation 10AAD(2) (at the end of the table)

Add:

13	For an export only biological, a change to information included in the entry in the Register for the export only biological	EX

11 At the end of subregulation 11A(1)

Add:

; and (c) an export only biological is separate and distinct from other biologicals if any of the following characteristics of the biological differ from other biologicals:

(i) active ingredient;

(ii) dosage form;

(iii) principal manufacturer.

12 At the end of subregulation 16V(1)

Add "or an export only biological".

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

Insert:

2AA	Application fee for the purposes of paragraph 32DCA(2)(c) of the Act for an application to include an export only biological in the Register	$1,231 for each application

Part 2—Clinical trials

Therapeutic Goods (Medical Devices) Regulations 2002

14 Paragraph 7.4(1)(a)

Omit "enter the", substitute "enter a".

15 Subregulation 10.7(1) (at the end of the definition of *initial decision*)

Add:

Note: See also subregulation (1A) of this regulation.

16 After subregulation 10.7(1)

Insert:

(1A) Each of the following decisions of the Secretary is an ***initial decision***:

(a) a decision to refuse to agree to a notification covered by paragraph (a) of the column headed "Conditions" in item 2.3 of the table in Part 2 of Schedule 4 being given before the end of a period nominated by the sponsor concerned;

(b) a decision to refuse to agree to a notification covered by paragraph (h) of the column headed "Conditions" in item 2.3 of the table in Part 2 of Schedule 4 being given before the end of a period nominated by the sponsor concerned.

17 Part 2 of Schedule 4 (table item 2.3, column headed "Kinds of medical devices")

After "used", insert "in a clinical trial".

18 Part 2 of Schedule 4 (table item 2.3, column headed "Conditions", paragraph (a))

Repeal the paragraph, substitute:

(a) The sponsor must notify the Secretary:

(i) in a form approved by the Secretary; and

(ii) in accordance with the requirements (if any) determined by the Secretary for the form of notification;

about the trial and the medical device covered by the trial and must do so before:

(iii) the medical device begins to be used in the trial, unless subparagraph (iv) applies; or

(iv) if the sponsor seeks the Secretary's agreement to the notification being given before the end of a period nominated by the sponsor and the Secretary agrees to this—the end of that nominated period.

19 Part 2 of Schedule 4 (at the end of the cell at table item 2.3, column headed "Conditions")

Add:

(h) The sponsor must notify the Secretary:

(i) in a form approved by the Secretary; and

(ii) in accordance with the requirements (if any) determined by the Secretary for the form of notification;

about any trial site not covered by the notification referred to in paragraph (a) and must do so before:

(iii) the medical device begins to be used at that site, unless subparagraph (iv) applies; or

(iv) if the sponsor seeks the Secretary's agreement to the notification being given before the end of a period nominated by the sponsor and the Secretary agrees to this—the end of that nominated period.

Therapeutic Goods Regulations 1990

20 Subregulation 12AC(1)

Omit "item 3 of the table in Schedule 5A", substitute "column 2 of item 3 of the table in Schedule 5A".

21 Paragraph 12AC(1)(a)

Omit "enter the", substitute "enter a".

22 Subregulation 48(1) (definition of *eligible person*, at the end of the table)

Add:

6	decision covered by subregulation (1AB)	the sponsor concerned

23 Subregulation 48(1) (note to the definition of *initial decision*)

Omit "subregulation (1AA)", substitute "subregulations (1AA) and (1AB)".

24 After subregulation 48(1AA)

Insert:

(1AB) Each of the following decisions of the Secretary is an ***initial decision***:

(a) a decision to refuse to agree to a notification covered by paragraph (a) of column 3 of item 3 of the table in Schedule 5A being given before the end of a period nominated by the sponsor concerned;

(b) a decision to refuse to agree to a notification covered by paragraph (ha) of column 3 of item 3 of the table in Schedule 5A being given before the end of a period nominated by the sponsor concerned.

25 Schedule 5A (table item 3, column 2)

Omit "used", substitute "to be used in a clinical trial".

26 Schedule 5A (table item 3, column 3, paragraph (a))

Repeal the paragraph, substitute:

(a) the sponsor must notify the Secretary:

(i) in a form approved by the Secretary; and

(ii) in accordance with the requirements (if any) determined by the Secretary for the form of notification;

about the trial and the therapeutic goods covered by the trial and must do so before:

(iii) the goods begin to be used in the trial, unless subparagraph (iv) applies; or

(iv) if the sponsor seeks the Secretary's agreement to the notification being given before the end of a period nominated by the sponsor and the Secretary agrees to this—the end of that nominated period; and

27 Schedule 5A (table item 3, column 3, paragraph (b))

Omit "must be accompanied by the relevant notification fee referred to in item 14 in Part 2 of Schedule 9 or item 17 of Schedule 9A", substitute "referred to in paragraph (a) must be accompanied by the relevant notification fee referred to in paragraph (a) of column 2 of item 14 in the table 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".

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

Insert:

(ha) the sponsor must notify the Secretary:

(i) in a form approved by the Secretary; and

(ii) in accordance with the requirements (if any) determined by the Secretary for the form of notification;

about any trial site not covered by the notification referred to in paragraph (a) and must do so before:

(iii) the goods begin to be used at that site, unless subparagraph (iv) applies; or

(iv) if the sponsor seeks the Secretary's agreement to the notification being given before the end of a period nominated by the sponsor and the Secretary agrees to this—the end of that nominated period; and

(hb) the notification referred to in paragraph (ha) must be accompanied by the relevant notification fee referred to in paragraph (b) of column 2 of item 14 in the table 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; and

Part 3—Delegations

Therapeutic Goods (Medical Devices) Regulations 2002

29 Paragraphs 10.6A(a) to (d)

Repeal the paragraphs, substitute:

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

Therapeutic Goods Regulations 1990

30 Subregulation 46A(2)

Repeal the subregulation, substitute:

(2) For the purposes of subsection 57(8) of the Act, the following positions are prescribed:
(a) an SES Band 1, 2 or 3 position;
(b) each position classified as a Medical Officer Class 3, 4, 5 or 6;
(c) an Executive Level 1 or 2 position.

Part 4—Australian conformity assessment bodies

Therapeutic Goods (Medical Devices) Regulations 2002

31 Subclause 3(2) of Schedule 3AA (table items 1 to 3)

Repeal the items, substitute:

1	(a) Union; or (b) national; or (c) Union and national	Australian
1A	(a) a Member State; or (b) the Member State; or (c) that Member State	Australia
2	(a) a competent authority; or (b) competent authorities; or (c) the Commission; or (d) the MDCG	the Secretary
3	notified body	Australian conformity assessment body
3A	notified bodies	Australian conformity assessment bodies

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

Add:

; or (c) this Annex

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

Repeal the item, substitute:

7	(a) general safety and performance requirements set out in Annex I; or (b) requirements in Annex I; or (c) requirements laid down in Annex I	essential principles

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

Omit "Annex", substitute "Annexes".

35 Subclause 3(2) of Schedule 3AA (table item 10)

Repeal the item.

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

Omit "the".

37 Subclause 3(2) of Schedule 3AA (table item 12)

Repeal the item.

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

Repeal the cell, substitute:

(a) post-market surveillance; or

(b) post-market surveillance plan

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

Add:

18	shall	must

40 At the end of subclause 3(3) of Schedule 3AA

Add:

Example: Item 4 of the table in subclause (2) does not apply to the reference to "authorised representative" in Section 4.3 of each EU regulation (see subparagraph (6)(c)(i) of this clause).

41 Subparagraph 3(6)(a)(i) of Schedule 3AA

Omit ", 1.2.8, 1.6.1, 3.2.1 and 4.5.6", substitute "and 1.2.8".

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

Repeal the subparagraphs, substitute:

(iii) the words "or previously applicable law within a notified body" in Section 3.2.3;

43 Subparagraph 3(6)(a)(viii) of Schedule 3AA

Repeal the subparagraph.

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

Repeal the paragraphs, substitute:

(b) in Section 3.1.1:

(i) the words "performance and safety of devices" are replaced with the words "compliance with the essential principles"; and

(ii) the words "those set out in Annex I" are replaced with the words "the essential principles";

(ba) in Section 3.3.1, the words "the authority responsible for notified bodies" are replaced with the words "the Secretary";

(c) in Section 4.3:

(i) a reference to an authorised representative is taken to be a reference to an applicant authorised by the manufacturer; and

(ii) a reference to the corresponding Annex is taken to be a reference to the corresponding part of Schedule 3 to these Regulations; and

(iii) the word "approval" is replaced with the word "assessment";

45 After paragraph 3(6)(d) of Schedule 3AA

Insert:

(da) in Section 4.5.2, the words "post-market surveillance information" are replaced with the words "information from post-marketing requirements mentioned in Schedule 3 to these Regulations";

46 After paragraph 3(6)(e) of Schedule 3AA

Insert:

(ea) in Section 4.6, the words "personnel in designating authorities" are replaced with the words "the Secretary";

47 Subparagraph 3(6)(f)(i) of Schedule 3AA

Repeal the subparagraph.

48 Subclauses 5(3) and (4) of Schedule 3AA

Repeal the subclauses, substitute:

(3) The EU medical devices regulation is modified in the following ways:

(a) the following provisions are disregarded:

(i) the last dash point of Section 1.1.6;

(ii) the words "the authorities responsible for notified bodies, competent authorities for medical devices in the Member States or" in Section 1.3.2;

(iii) the sentence "Refusals or withdrawals of applications shall be notified to the electronic system referred to in Article 57 and shall be accessible to other notified bodies." in Section 4.3;

(iv) the eighth dash point of Section 4.5.1;

(v) the words "referred to in Annexes II and III" in point (b) of Section 4.5.3;

(vi) the words "as specified in Section 15 of Annex XI" in point (d) of Section 4.5.3;

(vii) the words "as referred to in Regulation (EU) No 722/2012," in Section 4.5.6;

(viii) the words "for the relevant competent authority" in Section 4.5.6;

(ix) the words "under Article 92(2)" in Section 4.10;

(b) in Section 1.6.1, the words "notified body coordination group referred to in Article 49" are replaced with the word "Secretary";

(c) in Section 3.2.2, the words "Article 42(3)" are replaced with the words "Annex I of Commission Implementing Regulation (EU) 2017/2185 of 23 November 2017 on the list 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)";

(d) in point (a) of Section 4.5.3, the words "Part B of Annex XI" are replaced with the words "Part 3 of Schedule 3 to these Regulations";

(e) in point (b) of Section 4.5.3, the words "the EU" are replaced with the words "a relevant";

(f) in Section 4.5.5, the words "Annex XIV" (wherever occurring) are replaced with the words "Part 8 of Schedule 3 to these Regulations";

(g) in Section 4.5.6:

(i) 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

(ii) the words "that Regulation" are replaced with the words "these Regulations";

(h) in Section 4.10, 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".

49 Subclause 6(3) of Schedule 3AA

Repeal the subclause, substitute:

(3) The EU IVD regulation is modified in the following ways:

(a) the following provisions are disregarded:

(i) point (g) of Section 1.1.6;

(ii) the words "the authorities responsible for notified bodies, competent authorities for devices in the Member States or" in Section 1.3.2;

(iii) the sentence "Refusals or withdrawals of applications shall be notified to the electronic system referred to in Article 52 and shall be accessible to other notified bodies." in Section 4.3;

(iv) the subsection headed "Verification by examination and testing of every product batch" in Section 4.5.3;

(v) the paragraph beginning "In the case of companion diagnostics," in Section 4.5.5;

(vi) the words "under to Article 87" in Section 4.10;

(b) in Section 1.6.1, the words "notified body coordination group referred to in Article 49 of Regulation (EU) 2017/745" are replaced with the word "Secretary";

(c) in Section 3.2.2:

(i) 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 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 medical devices under Regulation (EU 2017/746 of the European Parliament and of the Council (Commission Implementing (EU) 2017/2185)"; and

(ii) the words "self and near patient testing" are replaced with the words "self-testing and point of care testing";

(d) in Section 4.5.5, the words "sufficient expertise and facilities for the procedures referred to in Section 5 of Annex IX, 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 the essential principles and these Regulations";

(e) in Section 4.10, 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";

(f) a reference to a class B device is taken to be a reference to a Class 2 IVD medical device;

(g) 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

50 Regulation 5.6

Repeal the regulation.

51 Subregulation 10.7(9) (note)

Omit "(*Gazette* No. S 342, 7 December 1994), accessible on the Internet at: http://scaleplus.law.gov.au/html/instruments/0/14/0/IN000020.htm".

Therapeutic Goods Regulations 1990

52 Subregulation 12B(1B) (table item 46)

Repeal the item.

Part 6—Application provisions

Therapeutic Goods (Medical Devices) Regulations 2002

53 In the appropriate position in Part 11

Insert:

Division 11.17—Application provisions relating to the Therapeutic Goods Legislation Amendment (2023 Measures No. 1) Regulations 2023

11.71 Clinical trials

The amendments of item 2.3 of the table in Part 2 of Schedule 4 made by Part 2 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2023 Measures No. 1) Regulations 2023* apply in relation to the use of a medical device on or after the commencement of those amendments, whether the clinical trial began before, on or after that commencement.

Therapeutic Goods Regulations 1990

54 In the appropriate position in Part 9

Insert:

Division 21—Application provisions relating to the Therapeutic Goods Legislation Amendment (2023 Measures No. 1) Regulations 2023

90 Clinical trials

The amendments of item 3 of the table in Schedule 5A made by Part 2 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2023 Measures No. 1) Regulations 2023* apply in relation to the use of therapeutic goods on or after the commencement of those amendments, whether the clinical trial began before, on or after that commencement.