



Therapeutic Goods Legislation Amendment (In Vitro Diagnostic Medical Devices) Regulation 2014

Select Legislative Instrument No. 63, 2014

I, General the Honourable Sir Peter Cosgrove AK MC (Ret'd),
Governor-General of the Commonwealth of Australia, acting with the
advice of the Federal Executive Council, make the following regulation.

Dated 29 May 2014

Peter Cosgrove
Governor-General

By His Excellency's Command

Fiona Nash
Assistant Minister for Health

OPC60403 - B

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1 Name of regulation

This regulation is the *Therapeutic Goods Legislation Amendment (In Vitro Diagnostic Medical Devices) Regulation 2014*.

2 Commencement

Each provision of this regulation 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
Provision(s)	Commencement
1. Sections 1 to 4 and anything in this regulation not elsewhere covered by this table	The day after this regulation is registered.
2. Schedules 1 and 2	1 July 2014
3. Schedule 3	At the end of 30 June 2014.

3 Authority

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

4 Schedule(s)

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

No. 63, 2014 *Therapeutic Goods Legislation Amendment (In Vitro Diagnostic Medical Devices) Regulation 2014* 1
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Schedule 1—Amendments of the Therapeutic Goods (Medical Devices) Regulations 2002

Part 1—Main amendments

Therapeutic Goods (Medical Devices) Regulations 2002

1 Part 11 (heading)

Repeal the heading, substitute:

Part 11—Transitional provisions

2 Before regulation 11.1

Insert:

Division 11.1—Transitional provisions relating to the Therapeutic Goods (Medical Devices) Amendment Regulations 2010 (No. 1)

Subdivision A—Preliminary

11.1 Interpretation

(1) In this Division:

2010 Amendment Regulations means the *Therapeutic Goods (Medical Devices) Amendment Regulations 2010 (No. 1)* as in force immediately before 1 July 2014.

approved transitional device means an IVD medical device (other than an in-house IVD medical device) that, immediately before 1 July 2010:

- (a) was a diagnostic good for in vitro use; and
- (b) was declared not to be a medical device under subsection 41BD(3) of the Act; and
- (c) was:

-
- (i) exempt from listing or registration under Part 3-2 of the Act because item 3 of Schedule 5A to the *Therapeutic Goods Regulations 1990* applied to the device; or
 - (ii) covered by an approval under paragraph 19(1)(b) of the Act; or
 - (iii) a device for which an application for approval under paragraph 19(1)(b) of the Act had been made but not finally determined.

diagnostic good for in vitro use has the same meaning as in the *Therapeutic Goods Regulations 1990* as in force on 30 June 2010.

exempt transitional device means an IVD medical device (other than an in-house IVD medical device) that, immediately before 1 July 2010:

- (a) was a diagnostic good for in vitro use; and
- (b) was declared not to be a medical device under subsection 41BD(3) of the Act; and
- (c) was exempt from listing or registration under Part 3-2 of the Act; and
- (d) was not a device to which item 3 of Schedule 5A to the *Therapeutic Goods Regulations 1990* applied.

listed or registered transitional device means an IVD medical device (other than an in-house IVD medical device) that, immediately before 1 July 2010:

- (a) was a diagnostic good for in vitro use; and
- (b) was declared not to be a medical device under subsection 41BD(3) of the Act; and
- (c) was:
 - (i) listed or registered under Part 3-2 of the Act; or
 - (ii) a device for which an effective application for listing or registration under Part 3-2 of the Act had been made but not finally determined.

Note: For circumstances in which an application under Part 3-2 of the Act is effective, see subsection 23(2) of the Act.

transitional device means:

- (a) a Class 1 in-house IVD medical device; or
- (b) a Class 2 in-house IVD medical device; or

- (c) a Class 3 in-house IVD medical device; or
- (d) a Class 4 in-house IVD medical device; or
- (e) a listed or registered transitional device; or
- (f) an approved transitional device; or
- (g) an exempt transitional device.

transitional period means:

- (a) for a transitional device that is not an in-house IVD medical device—the period starting on 1 July 2014 and ending immediately before the transition day for the device; and
- (b) for a transitional device that is an in-house IVD medical device—the period starting on the later of:
 - (i) 1 July 2014; and
 - (ii) the day the device comes into existence;and ending immediately before the transition day for the device.

transition day, for a transitional device, means the day on which Schedule 1 to the 2010 Amendment Regulations starts to apply, for all purposes, in relation to the device.

Meaning of finally determined

- (2) For this Division, an application is ***finally determined*** at the first time both the following conditions are met:
 - (a) a decision has been made not to grant the application;
 - (b) there is no longer any possibility of a change in the outcome of the decision.
- (3) For paragraph (2)(b), the possibility of a discretion being exercised after the period has ended, to extend the period for seeking review by a court or tribunal of the decision or for starting other proceedings (including appeals) arising out of the application, decision or review, is not to be considered.

References to including a device in the Register

- (4) In this Division, a reference to including a device in the Register is a reference to including the device in the Register under Chapter 4 of the Act.

11.2 Application of 2010 Amendment Regulations

- (1) The amendments made by Schedule 1 to the 2010 Amendment Regulations apply in relation to a transitional device as set out in Subdivisions C to F of this Division unless:
 - (a) the device was included in the Register before 1 July 2014;
or
 - (b) an effective application for including the device in the Register was made before 1 July 2014 and the application was finally determined before that date.
- (2) To avoid doubt, the amendments made by Schedule 1 to the 2010 Amendment Regulations apply, for all purposes, on and after 1 July 2014 in relation to:
 - (a) a transitional device covered by paragraph (1)(a); and
 - (b) a transitional device covered by paragraph (1)(b); and
 - (c) an IVD medical device that is not a transitional device.

Subdivision B—General provisions relating to transitional devices

11.3 Application of this Subdivision

This Subdivision applies in relation to a transitional device unless:

- (a) the device was included in the Register before 1 July 2014;
or
- (b) an effective application for including the device in the Register was made before 1 July 2014 and the application was finally determined before that date.

11.4 Transitional devices exempted from requirement to be included in the Register

- (1) For paragraph 41HA(1)(b) of the Act, a transitional device is exempt from the operation of Division 3 of Part 4-11 of the Act during the transitional period for the device.
- (2) Subregulation 7.1(3) does not apply in relation to a transitional device during the transitional period for the device.

- (3) Regulation 3.10 does not apply in relation to a transitional device, during the transitional period for the device, for a purpose connected with:
- (a) an application for a conformity assessment certificate in respect of the device; or
 - (b) issuing a conformity assessment certificate in respect of the device; or
 - (c) an application for including the device in the Register; or
 - (d) including the device in the Register.

11.5 Essential principles for transitional devices

- (1) For section 41CA of the Act, the essential principles set out in clauses 3 and 6 of Schedule 1 to these Regulations, as in force immediately before 1 July 2010, are prescribed for a transitional device during the transitional period for the device, for a purpose other than a purpose mentioned in subregulation (2).
- (2) Regulation 2.1 and Schedule 1 to these Regulations as in force on and after 1 July 2010 apply in relation to a transitional device for a purpose connected with:
- (a) an application for a conformity assessment certificate in respect of the device; or
 - (b) issuing a conformity assessment certificate in respect of the device; or
 - (c) an application for including the device in the Register; or
 - (d) including the device in the Register;
- and not for any other purpose, during the transitional period for the device.

Subdivision C—Listed or registered transitional devices and exempt transitional devices

11.6 Application of this Subdivision

This Subdivision applies in relation to the following devices:

- (a) a listed or registered transitional device;
- (b) an exempt transitional device.

11.7 Application of 2010 Amendment Regulations—certain purposes

The amendments made by Schedule 1 to the 2010 Amendment Regulations apply in relation to the device, on and after 1 July 2014, for purposes connected with:

- (a) an application for a conformity assessment certificate in respect of the device; or
- (b) issuing a conformity assessment certificate in respect of the device; or
- (c) an application for including the device in the Register; or
- (d) including the device in the Register.

11.8 Application of 2010 Amendment Regulations—conformity assessment certificate required and applied for before 1 September 2014

- (1) This regulation applies in relation to the device if:
 - (a) a conformity assessment certificate is required under section 41EA of the Act before an effective application for including the device in the Register may be made; and
 - (b) an effective application for a conformity assessment certificate in respect of the device is made before 1 September 2014.

Certificate issued and inclusion application made before 1 July 2015—device included in Register

- (2) If:
 - (a) a conformity assessment certificate in respect of the device is issued before 1 June 2015; and
 - (b) an effective application for including the device in the Register is made before 1 July 2015; and
 - (c) the device is included in the Register;

the amendments made by Schedule 1 to the 2010 Amendment Regulations apply in relation to the device, for all purposes, on and after the day the device is included in the Register.

Note: For circumstances in which an application for a medical device to be included in the Register under Chapter 4 of the Act is effective, see subsection 41FC(2) of the Act.

*Certificate issued and inclusion application made before 1 July
2015—device not included in Register*

- (3) If:
- (a) a conformity assessment certificate in respect of the device is issued before 1 June 2015; and
 - (b) an effective application for including the device in the Register is made before 1 July 2015; and
 - (c) the application for including the device in the Register is finally determined;

the amendments made by Schedule 1 to the 2010 Amendment Regulations apply in relation to the device, for all purposes, on and after the day the application for including the device in the Register is finally determined.

*Certificate issued but inclusion application not made before 1 July
2015*

- (4) If:
- (a) a conformity assessment certificate in respect of the device is issued before 1 June 2015; and
 - (b) an effective application for including the device in the Register is not made before 1 July 2015;

the amendments made by Schedule 1 to the 2010 Amendment Regulations apply in relation to the device, for all purposes, on and after 1 July 2015.

*Certificate issued on or after 1 June 2015 and inclusion
application made within 30 days—device included in Register*

- (5) If:
- (a) a conformity assessment certificate in respect of the device is issued on or after 1 June 2015; and
 - (b) an effective application for including the device in the Register is made no later than 30 days after the day the certificate is issued; and
 - (c) the device is included in the Register;

the amendments made by Schedule 1 to the 2010 Amendment Regulations apply in relation to the device, for all purposes, on and after the day the device is included in the Register.

Certificate issued on or after 1 June 2015 and inclusion application made within 30 days—device not included in Register

- (6) If:
- (a) a conformity assessment certificate in respect of the device is issued on or after 1 June 2015; and
 - (b) an effective application for including the device in the Register is made no later than 30 days after the day the certificate is issued; and
 - (c) the application for including the device in the Register is finally determined;

the amendments made by Schedule 1 to the 2010 Amendment Regulations apply in relation to the device, for all purposes, on the day the application for including the device in the Register is finally determined.

Certificate issued on or after 1 June 2015 but inclusion application not made within 30 days

- (7) If:
- (a) a conformity assessment certificate in respect of the device is issued on or after 1 June 2015; and
 - (b) an effective application for including the device in the Register is not made within 30 days after the day the certificate is issued;

the amendments made by Schedule 1 to the 2010 Amendment Regulations apply in relation to the device, for all purposes, 30 days after the day the certificate is issued.

Certificate application finally determined and certificate not issued

- (8) If the application for the conformity assessment certificate is finally determined, the amendments made by Schedule 1 to the 2010 Amendment Regulations apply in relation to the device, for all purposes, on and after the day the application for the certificate is finally determined.

**11.9 Application of 2010 Amendment Regulations—conformity
assessment certificate required but not applied for before
1 September 2014**

If:

- (a) a conformity assessment certificate is required under section 41EA of the Act before an effective application for including the device in the Register may be made; and
- (b) an effective application for a conformity assessment certificate in respect of the device is not made before 1 September 2014;

the amendments made by Schedule 1 to the 2010 Amendment Regulations apply in relation to the device, for all purposes, on and after 1 September 2014.

**11.10 Application of 2010 Amendment Regulations—conformity
assessment certificate not required**

- (1) This regulation applies in relation to the device if a conformity assessment certificate is not required under section 41EA of the Act before an effective application for including the device in the Register may be made.

Inclusion application made before 1 July 2015—device included in Register

(2) If:

- (a) an effective application for including the device in the Register is made before 1 July 2015; and
- (b) the device is included in the Register;

the amendments made by Schedule 1 to the 2010 Amendment Regulations apply in relation to the device, for all purposes, on and after the day the device is included in the Register.

Inclusion application made before 1 July 2015—device not included in Register

(3) If:

- (a) an effective application for including the device in the Register is made before 1 July 2015; and

(b) the application for including the device in the Register is finally determined;

the amendments made by Schedule 1 to the 2010 Amendment Regulations apply in relation to the device, for all purposes, on and after the day the application for including the device in the Register is finally determined.

Inclusion application not made before 1 July 2015

- (4) If an effective application for including the device in the Register is not made before 1 July 2015, the amendments made by Schedule 1 to the 2010 Amendment Regulations apply in relation to the device, for all purposes, on and after 1 July 2015.

11.11 Cancellation of listing or registration

If a listed or registered transitional device is listed or registered under Part 3-2 of the Act immediately before 1 July 2014, the listing or registration is taken to be cancelled on the transition day for the device.

Subdivision D—Approved transitional devices

11.12 Application of this Subdivision

This Subdivision applies in relation to an approved transitional device.

11.13 Application of 2010 Amendment Regulations—certain purposes

The amendments made by Schedule 1 to the 2010 Amendment Regulations apply in relation to an approved transitional device, on and after 1 July 2014, for purposes connected with:

- (a) an application for a conformity assessment certificate in respect of the device; or
- (b) issuing a conformity assessment certificate in respect of the device; or
- (c) an application for including the device in the Register; or
- (d) including the device in the Register.

11.14 Application of 2010 Amendment Regulations—all purposes

The amendments made by Schedule 1 to the 2010 Amendment Regulations apply in relation to an approved transitional device, for all purposes, on and after:

- (a) if the device is covered by subparagraph (c)(i) of the definition of *approved transitional device* in subregulation 11.1(1)—the day the device ceases to be a device to which item 3 of Schedule 5A to the *Therapeutic Goods Regulations 1990* applies; and
- (b) if the device is covered by subparagraph (c)(ii) of the definition of *approved transitional device* in subregulation 11.1(1)—the day the approval for the device ceases to have effect; and
- (c) if the device is covered by subparagraph (c)(iii) of the definition of *approved transitional device* in subregulation 11.1(1):
 - (i) if approval is given for the device under paragraph 19(1)(b) of the Act—the day the approval ceases to have effect; and
 - (ii) in any other case—the day the application for approval is finally determined.

Subdivision E—Class 4 in-house IVD medical devices

11.15 Application of this Subdivision

This Subdivision applies in relation to a Class 4 in-house IVD medical device.

11.16 Application of 2010 Amendment Regulations—certain purposes

The amendments made by Schedule 1 to the 2010 Amendment Regulations apply in relation to the device on and after the later of the following days:

- (a) 1 July 2014;
 - (b) the day on which the device comes into existence;
- for purposes connected with:

- (c) an application for a conformity assessment certificate in respect of the device; or
- (d) issuing a conformity assessment certificate in respect of the device; or
- (e) an application for including the device in the Register; or
- (f) including the device in the Register.

11.17 Application of 2010 Amendment Regulations—conformity assessment certificate applied for before 1 July 2016

- (1) This regulation applies in relation to the device if:
 - (a) the device is in existence immediately before 1 July 2016; and
 - (b) an application for a conformity assessment certificate in respect of the device is made before 1 July 2016.

Certificate issued and inclusion application made before 1 July 2017—device included in Register

- (2) If:
 - (a) a conformity assessment certificate in respect of the device is issued before 1 June 2017; and
 - (b) an effective application for including the device in the Register is made before 1 July 2017; and
 - (c) the device is included in the Register;the amendments made by Schedule 1 to the 2010 Amendment Regulations apply in relation to the device, for all purposes, on and after the day the device is included in the Register.

Note: For circumstances in which an application for a medical device to be included in the Register under Chapter 4 of the Act is effective, see subsection 41FC(2) of the Act.

Certificate issued and inclusion application made before 1 July 2017—device not included in Register

- (3) If:
 - (a) a conformity assessment certificate in respect of the device is issued before 1 June 2017; and
 - (b) an effective application for including the device in the Register is made before 1 July 2017; and

- (c) the application for including the device in the Register is finally determined;

the amendments made by Schedule 1 to the 2010 Amendment Regulations apply in relation to the device, for all purposes, on and after the day the application for including the device in the Register is finally determined.

Certificate issued but inclusion application not made before 1 July 2017

- (4) If:

- (a) a conformity assessment certificate in respect of the device is issued before 1 June 2017; and

- (b) an effective application for including the device in the Register is not made before 1 July 2017;

the amendments made by Schedule 1 to the 2010 Amendment Regulations apply in relation to the device, for all purposes, on and after 1 July 2017.

Certificate issued on or after 1 June 2017 and inclusion application made within 30 days—device included in Register

- (5) If:

- (a) a conformity assessment certificate in respect of the device is issued on or after 1 June 2017; and

- (b) an effective application for including the device in the Register is made no later than 30 days after the day the certificate is issued; and

- (c) the device is included in the Register;

the amendments made by Schedule 1 to the 2010 Amendment Regulations apply in relation to the device, for all purposes, on and after the day the device is included in the Register.

Certificate issued on or after 1 June 2017 and inclusion application made within 30 days—device not included in Register

- (6) If:

- (a) a conformity assessment certificate in respect of the device is issued on or after 1 June 2017; and

(b) an effective application for including the device in the Register is made no later than 30 days after the day the certificate is issued; and

(c) the application for including the device in the Register is finally determined;

the amendments made by Schedule 1 to the 2010 Amendment Regulations apply in relation to the device, for all purposes, on the day the application for including the device in the Register is finally determined.

Certificate issued on or after 1 June 2017 and inclusion application not made within 30 days

(7) If:

(a) a conformity assessment certificate in respect of the device is issued on or after 1 June 2017; and

(b) an effective application for including the device in the Register is not made within 30 days after the day the certificate is issued;

the amendments made by Schedule 1 to the 2010 Amendment Regulations apply in relation to the device, for all purposes, 30 days after the day the certificate is issued.

Certificate application finally determined and certificate not issued

(8) If the application for the conformity assessment certificate is finally determined, the amendments made by Schedule 1 to the 2010 Amendment Regulations apply in relation to the device, for all purposes, on the day the application for the certificate is finally determined.

11.18 Application of 2010 Amendment Regulations—conformity assessment certificate not applied for before 1 July 2016

If:

(a) the device is in existence immediately before 1 July 2016; and

(b) an effective application for a conformity assessment certificate in respect of the device is not made before 1 July 2016;

the amendments made by Schedule 1 to the 2010 Amendment Regulations apply in relation to the device, for all purposes, on and after 1 July 2016.

11.19 Devices coming into existence on or after 1 July 2016

If the device comes into existence on or after 1 July 2016, the amendments made by Schedule 1 to the 2010 Amendment Regulations apply in relation to the device, for all purposes, on and after the day the device comes into existence.

Subdivision F—Class 1, 2 and 3 in-house IVD medical devices

11.20 Application of this Subdivision

This Subdivision applies in relation to the following medical devices:

- (a) a Class 1 in-house IVD medical device;
- (b) a Class 2 in-house IVD medical device;
- (c) a Class 3 in-house IVD medical device.

11.21 Application of 2010 Amendment Regulations for all purposes

The amendments made by Schedule 1 to the 2010 Amendment Regulations apply in relation to the device, for all purposes, on and after the later of:

- (a) 1 July 2017; and
- (b) the day the device comes into existence.

Division 11.2—Transitional provisions relating to the Therapeutic Goods (Medical Devices) Amendment Regulation 2012 (No. 1)

3 Regulation 11.1

Renumber as regulation 11.22.

Part 2—Other amendments

Therapeutic Goods (Medical Devices) Regulations 2002

4 Subclause 1.2(1) of Part 6A of Schedule 3

Omit “1 July 2014”, substitute “1 July 2017”.

Schedule 2—Amendments of the Therapeutic Goods Regulations 1990

Therapeutic Goods Regulations 1990

1 Before regulation 49

Insert:

Division 1—Transitional provisions relating to the Therapeutic Goods Amendment Regulations 2010 (No. 1)

48A Definitions

In this Division:

2010 Amendment Regulations means the *Therapeutic Goods Amendment Regulations 2010 (No. 1)*.

finally determined has the same meaning as in Division 11.1 of Part 11 of the *Therapeutic Goods (Medical Devices) Regulations 2002*.

transitional device has the same meaning as in Division 11.1 of Part 11 of the *Therapeutic Goods (Medical Devices) Regulations 2002*.

transition day, for a transitional device, has the same meaning as in Division 11.1 of Part 11 of the *Therapeutic Goods (Medical Devices) Regulations 2002*.

48B Application of 2010 Amendment Regulations

- (1) The amendments made by Schedule 1 to the 2010 Amendment Regulations apply in relation to a transitional device on and after the transition day for the device.
- (2) However, to avoid doubt, if:
 - (a) a transitional device was included in the Register under Chapter 4 of the Act before 1 July 2014; or

(b) an effective application for including a transitional device in the Register under Chapter 4 of the Act was made before 1 July 2014 and the application was finally determined before that date;

the amendments made by Schedule 1 to the 2010 Amendment Regulations apply in relation to the device on and after 1 July 2014.

**Division 2—Transitional provisions relating to the
Therapeutic Goods Amendment Regulation 2012
(No. 3)**

2 Regulation 49

Omit “(No.)”, substitute, “(No. 3)”.

Schedule 3—Repeal

Therapeutic Goods Amendment Regulations 2010 (No. 1)

1 The whole of the Regulations

Repeal the Regulations.

Therapeutic Goods (Medical Devices) Amendment Regulations 2010 (No. 1)

2 The whole of the Regulations

Repeal the Regulations.