

## EXPLANATORY STATEMENT

### Select Legislative Instrument No. 63, 2014

Subject: *Therapeutic Goods Act 1989*

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

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

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

In vitro diagnostic medical devices (IVDs) are medical devices intended by the manufacturer to be used in vitro ('in glass') for the examination of specimens derived from the human body. They are, in general, pathology tests and related instrumentation used to carry out testing on human samples, where the results are intended to assist in clinical diagnosis or in making decisions concerning clinical management. IVDs are typically used in diagnostic laboratories, at the point of care and in the home, and can be commercially manufactured products or tests developed 'in-house' by a laboratory.

On 1 July 2010, a new, tailored, regulatory framework for IVDs was introduced. Under this new framework IVDs are regulated as medical devices under Chapter 4 of the Act. Previously IVDs had been regulated as therapeutic devices under Part 3-2 of the Act. Some were registered or listed in the Australian Register of Therapeutic Goods (the Register), some were exempt from registration or listing and some were approved for limited uses (for instance in clinical trials).

Under transitional provisions included in the *Therapeutic Goods (Medical Devices) Amendment Regulations 2010 (No. 1)* (the 2010 MD Amendments), IVDs in existence immediately before 1 July 2010 were given until 30 June 2014 to make the transition to the new framework. IVDs that were exempt or approved for a particular purpose (such as use in clinical trials) could continue to be supplied until the end of the trial. In-house IVDs (which are developed and used in laboratories or laboratory networks and not supplied to third parties) were given until 1 July 2014 to make the transition.

It has become apparent through contact with industry, that there is a need for more time to assist sponsors and manufacturers of IVDs to migrate successfully to the new framework, and in particular to compile the full range of documentation needed under Chapter 4 of the Act to support the safety and performance of their devices, for example in relation to their manufacturing processes and the design of their products. Without changes to the current transitional arrangements, there may be a risk that the supply of IVDs in Australia could be interrupted.

The purpose of the Regulation is therefore to extend the current deadline for submitting an application to the TGA for the inclusion of an IVD in the Register. The Regulation also includes special provisions for IVDs in relation to which a conformity assessment certificate must be issued by the TGA before an application for marketing approval can be made.

The *Therapeutic Goods (Medical Devices) Regulations 2002* set out which IVDs are required to have a conformity assessment certificate issued before an application for their inclusion in the Register can be made. These certificates are issued by the TGA, and signify a range of matters about the manufacture of the devices to which they relate, including that they comply with minimum requirements for performance and safety, and that relevant manufacturing standards are being observed.

In summary, the Regulation requires sponsors of transitioning commercial IVDs that have not already done so to apply for a conformity assessment certificate by 1 September 2014 in order to qualify for the extension of the transition period to 30 June 2015. For Class 4 in-house IVDs, manufacturers are required to apply for a conformity assessment certificate by 30 June 2016 in order to qualify for the extension of the transition period to 30 June 2017.

Allowing manufacturers of in-house IVDs a longer period to transition to the new framework reflects the fact that in-house IVDs are often adaptations of commercial IVDs that are further developed by laboratories for their own internal use. Thus the commercial IVDs on which they are based must be included in the Register before the adapted in-house IVDs can themselves transition to the new framework.

The only IVDs which are not covered by the new transitional provisions are those which have already been included in the Register as medical devices under Chapter 4 of the Act, or in relation to which a decision to reject an application to include them in the Register as medical devices has already finally determined.

The Regulation repeals the 2010 MD Amendments and the *Therapeutic Goods Amendment Regulations 2010 (No.1)*.

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

The Act does not specify conditions that need to be met before the power to make the Regulation may be exercised.

The Regulation is a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.

Sections 1 to 4 of the Regulation commence the day after the regulation is registered, Schedules 1 and 2 commence on 1 July 2014, and Schedule 3 (which repeals the two 2010 regulations mentioned above), commences at the end of 30 June 2014.

## **Consultation**

Over the last twelve months, the TGA has consulted extensively about the extension of the transition period for IVDs. In May 2013 the TGA released a public consultation paper that included the possible extension of the transition timeframe, inviting feedback from industry, healthcare providers and the community on that proposal. Over the same period, further discussions were held with key stakeholder groups, peak industry bodies, sponsors and

manufacturers. These included, for example, the National Association of Testing Authorities (NATA), IVD Australia, the Biotherapeutics Association of Australasia (Inc) and the Australian Red Cross Blood Service. Also during that period, the TGA surveyed the commercial and in-house IVD sectors to identify further information in particular about IVDs that might be at risk of not transitioning to the new framework. More recently, the TGA has undertaken further discussion on the extension (and new deadlines) with industry representatives at an IVD working group meeting that was held in Canberra on 8 May 2014. Responses to these consultations indicated broad support for delaying the implementation of the IVD framework, and support for an additional period of time to be provided for the in-house sector to transition

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

**Details of the *Therapeutic Goods Legislation Amendment (In Vitro Diagnostic Medical Devices) Regulation 2014***

**Section 1 – Name of regulation**

This section provides for the regulation to be referred to as the *Therapeutic Goods Legislation Amendment (In Vitro Diagnostic Medical Devices) Regulation 2014*.

**Section 2 – Commencement**

This section provides for:

- sections 1 to 4 and any provisions not elsewhere provided for, to commence the day after the regulation is registered,
- Schedules 1 and 2 to commence on 1 July 2014, and
- Schedule 3 to commence at the end of 30 June 2014.

This will ensure that there is no overlap of the repeal of the *Therapeutic Goods (Medical Devices) Amendment Regulations 2010 (No.1)* (the 2010 MD Amendments) and of the *Therapeutic Goods Amendment Regulations 2010 (No.1)* (the 2010 TG Amendments) with the amendments of the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Principal Regulations) in Schedule 1 and of the *Therapeutic Goods Regulations 1990* in Schedule 2. The effect is that the transitional devices that were not included in the Register between 1 July 2010 and 30 June 2014 or in relation to which an application for inclusion in the Register was finally determined during that period, are covered by these new amendments.

**Section 3 – Authority**

This section provides that the regulation is made under the *Therapeutic Goods Act 1989* (the Act).

**Section 4 – Schedule(s)**

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 of the *Therapeutic Goods (Medical Devices) Regulations 2002***

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

**Part 1 – Main amendments**

**Item 1 – Part 11 (heading)**

This item makes a minor change to the current heading of Part 11 of the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Principal Regulations) to accommodate item 2 below.

**Item 2 – Before regulation 11.1 (new Division 11.1 – Transitional provisions relating to the *Therapeutic Goods (Medical Devices) Amendment Regulations 2010 (No.1)*)**

**Summary of changes in item**

This item introduces a new Division 11.1 to replace, from 1 July 2014, the current transitional arrangements for in vitro diagnostic medical devices (IVDs) - set out (principally) in the 2010

MD Amendments – with new transitional arrangements (Schedule 3 of this Regulation repeals the 2010 MD Amendments from the last moment in time on 30 June 2014, to ensure a seamless changeover from the current, to the new, transitional arrangements).

The 2010 MD Amendments introduced a new regulatory framework for IVDs under which these products are regulated as medical devices under Chapter 4 of the Act rather than as therapeutic devices under Part 3-2 of the Act. The 2010 TG Amendments made a number of consequential changes to the Therapeutic Goods Regulations 1990 at the same time.

The transitional arrangements in the 2010 MD Amendments delayed the application of the new framework (set out in Schedule 1 to the 2010 MD Amendments):

- for IVDs (commercial IVDs) that were in existence immediately before 1 July 2010, until (i.e. up to and including) 30 June 2014; and
- for in-house IVDs that were in existence immediately before 1 July 2010 and for in-house IVDs that came into existence during the period 1 July 2010 to 30 June 2014, until (i.e. up to and including) 30 June 2014.

The principal effect of the amendments in item 2 is to extend this delayed application of the new framework until 30 June 2015 for commercial IVDs, and until 30 June 2017 for in-house IVDs - thus allowing them to continue to be supplied until the time they are included in the Register as medical devices under Chapter 4 of the Act.

However, in order to qualify for the full extension:

- sponsors of IVDs that are required under regulation 4.1 of the Principal Regulations to obtain a conformity assessment certificate from the TGA before an application can be made for inclusion of the IVD in the Register (and thus marketing approval), are required to apply for such a certificate by a specified deadline (for commercial IVDs, this is 1 September 2014, and for Class 4 in-house IVDs this is 1 July 2016); and
- that certificate is issued by the TGA.

Regulation 4.1 of the Principal Regulations sets out which IVDs must have a conformity assessment certificate issued by the TGA before an application for their inclusion in the Register can be made. These are IVDs manufactured in Australia (other than Class 1 commercial IVDs and Class 1-3 in-house IVDs), and all Class 4 IVDs.

If the conformity assessment certificate in relation to a commercial IVD was issued by the TGA on or after 1 June 2015, an application for the inclusion of the relevant IVD in the Register has to be made within 30 days of the issuing of the certificate. If the certificate in relation to a Class 4 in-house IVD was issued on or after 1 June 2017, an application for the inclusion of the relevant IVD in the Register has to be made within 30 days of the issuing of the certificate.

For IVDs in relation to which a conformity assessment certificate is not required, an application for inclusion in the Register has to be made:

- for commercial IVDs – by 1 July 2015; and
- for in-house IVDs – by 1 July 2017.

The basic rule underlying the provisions included in the Principal Regulations by item 2 is that commercial IVDs that are subject to the transitional arrangements could continue to be supplied on and after 1 July 2014:

- if those IVDs were supplied for the purposes of an approved or exempt clinical trial – until the clinical trial ends;
- for all other commercial IVDs and Class 4 in-house IVDs – until:
  - the IVD is included in the Register under Chapter 4 of the Act as a medical device;
  - it has been finally determined that a conformity assessment certificate will not be issued;
  - an application for inclusion of the device in the Register is not made in time; or
  - such an application is finally determined to be rejected.

The basic rule in relation to Class 1, 2 and 3 in-house IVDs - that do not require a conformity assessment certificate - is that they could not be supplied after 1 July 2017 unless they comply with the new IVD framework applying to them from that date.

The new Division 11.1 introduced by item 2 contains new Subdivisions A – F.

#### **Subdivision A – Preliminary**

This Subdivision defines a number of the key terms used in new Division 11.

This includes a definition of ‘transitional period’ and ‘transition day’, in relation to commercial and in-house IVDs. These definitions reflect that under this Regulation the point at which a transitional device becomes subject to the new IVD framework differs depending on a number of factors. These include, for example, whether a conformity assessment certificate is required before an application can be made to include the device in the Register under Chapter 4 of the Act, whether an application is made for a certificate by the date as set out in the regulation, and whether an application for inclusion of the device in the Register is made by the date required under the regulation. Regulations 11.8-11.10, 11.14, 11.17-11.19 and 11.21 set out a range of different dates for these purposes.

Regulation 11.1 sets out when an application is taken to be ‘finally determined’ – it is the first time that both the following conditions are met - when a decision has been made not to grant the application and there is no longer any possibility of a change in the outcome of the decision. For instance:

- if there is an initial decision by the TGA to reject an application for a conformity assessment certificate under the regulations, that decision is ‘finally determined’ (see for instance subregulation 11.7(8)) if the unsuccessful applicant had not sought an internal review of that decision under section 60 of the Act within the 90 days allowed for under that section; and
- if there is a decision by the TGA to reject an application to include an IVD in the Register and the unsuccessful applicant seeks an internal review under section 60 of the Act and is again unsuccessful, the decision is only ‘finally determined’ if either the applicant had not sought to have that decision reviewed by the Administrative Appeals Tribunal (AAT) within the 28 days provided for under the *Administrative Appeals Tribunal Act 1975*, or had done so and the AAT had decided to uphold the internal review decision.

The concept of an application being ‘finally determined’ is not relevant if at any time the application is successful i.e. the conformity assessment certificate is granted or the relevant IVD is included in the Register.

Regulation 11.2 makes it clear that the amendments made by Schedule 1 of the 2010 MD Amendments apply for all purposes on and after 1 July 2014 to:

- transitional devices that, between 1 July 2010 and 30 June 2014, were included in the Register as medical devices (in other words, that had already made the transition to the new IVD framework) or in relation to which a decision made to reject an application to include them in the Register as medical devices had been finally determined during that period, and
- any IVD that is not a transitional device (i.e. a commercial device) that came into existence on or after 1 July 2010.

(All in-house IVDs are taken to be ‘transitional devices’, irrespective of when they come into existence and are covered by Subdivisions E and F – see paragraphs (a) to (d) of the definition of ‘transitional device’ in subregulation 11.1(1).)

### **Subdivision B – General provisions relating to transitional devices**

This Subdivision sets out a number of matters relating to transitional devices during the transitional period.

#### **Exemption from inclusion in the Register, and application of conformity assessment procedures, during transitional period**

Subdivision B makes it clear that transitional devices are exempt, under section 41HA of the Act and subregulation 11.4(1), from the requirement to be included in the Register as a medical device under Chapter 4 of the Act during the transition period for the device. This is to ensure that provisions in Chapter 4 of the Act that otherwise apply to the device do not apply for so long as it is within the transitional period for the device as described above.

It is important to note, however, that this does not preclude sponsors of transitional devices from applying for the inclusion of their products in the Register as medical devices during this period. This is because subregulations 11.7, 11.13 and 11.16 each have the effect (for different kinds of transitional devices) of applying the new framework for IVDs during the transitional period for *certain* purposes, including for the purposes of applying for inclusion in the Register as a medical device. For instance, a sponsor applying to include their IVD in the Register during the transition period is required to certify under section 41 FD of the Act that an appropriate conformity assessment procedure had been applied to their device. The ‘appropriate’ procedure is determined by reference to the Principal Regulations as amended by Schedule 1 to the 2010 MD Regulations. As such, those provisions in that schedule have to apply in order for the sponsor to make that certification.

#### **Essential principles during transition period**

Subregulation 11.5(1) specifies essential principles that apply to a transitional device during the transition period for the device – these are essential principles 3 and 6, which are set out in Part 1 of Schedule 3 to the Principal Regulations as they were in force immediately before 1 July 2010 (i.e. before the IVD framework came into operation). Essential principles are mandatory requirements or standards that apply to medical devices, and provide minimum benchmarks relating to the safety and performance of devices. This is necessary to ensure that the device can continue to be supplied lawfully during the transition period for the device.

Subregulation 11.5(2) ensures that when, during the transition period, the sponsor of a transitional device applies for a conformity assessment certificate or to include its device in the Register as a medical device, is required to demonstrate (or certify as to) the compliance of its product with the essential principles, by reference to the requirements of the new, IVD-specific regulatory framework introduced by Schedule 1 to the 2010 MD Amendments.

**Subdivision C – Listed or registered transitional devices and exempt transitional devices**

This Subdivision applies to transitional devices that, immediately before 1 July 2010, were in the Register as listed or registered therapeutic devices or were exempt from registration or listing (other than for use in a clinical trial) - except any such IVDs excluded from these new transitional arrangements by regulation 11.3.

Regulation 11.7 applies the new IVD framework for such IVDs for the purposes of applying for, or being issued, a conformity assessment certificate or applying for inclusion, or being included, in the Register.

This makes it clear that, while transitional devices are exempt from inclusion in the Register under Chapter 4 during the transition period, sponsors of these products are able to apply for a conformity assessment certificate, and apply to have IVDs included in the Register as medical devices under Chapter 4, during the transitional period. This amendment also ensures that when sponsors do so, their applications are assessed by reference to the IVD-specific requirements of the new framework.

Regulations 11.8-11.10 set out when listed or registered transitional devices, and exempt transitional devices, are subject to the new framework for all purposes, depending on the particular circumstances applying in relation to the device.

**Table 1** summarises each of these circumstances, identifying when each type of IVD subject to the new framework.

**Table 1**



New provision	Scenario	Transition day - when new framework applies
	Where a conformity assessment certificate (CAC) is required to be issued before an application can be made for inclusion of the device in the Register: <sup>1</sup>	
11.8(2)	<ul style="list-style-type: none"> <li>• an effective application for CAC<sup>2</sup> is made before 1 September 2014</li> <li>• CAC is issued by TGA before 1 June 2015</li> <li>• an effective application for inclusion in the Register<sup>3</sup> is made before 1 July 2015</li> <li>• device is included in the Register.</li> </ul>	The day the device is included in the Register.
11.8(3)	<ul style="list-style-type: none"> <li>• an effective application for CAC is made before 1 September 2014</li> <li>• CAC is issued by TGA before 1 June 2015</li> <li>• an effective application for inclusion in the Register is made before 1 July 2015</li> <li>• the application is finally determined (i.e. is not granted, and there is no longer any possibility of a change in that outcome).</li> </ul>	The day the application for inclusion is finally determined.
11.8(4)	<ul style="list-style-type: none"> <li>• an effective application for CAC is made before 1 September 2014</li> <li>• CAC is issued by TGA before 1 June 2015</li> <li>• no effective application for inclusion in the Register is made before 1 July 2015.</li> </ul>	1 July 2015.
11.8(5)	<ul style="list-style-type: none"> <li>• an effective application for CAC is made before 1 September 2014</li> <li>• CAC is issued by TGA on or after 1 June 2015</li> <li>• an effective application for inclusion in the Register is made within 30 days after CAC issued</li> <li>• the device is included in the Register.</li> </ul>	The day the device is included in the Register.
11.8(6)	<ul style="list-style-type: none"> <li>• an effective application for CAC is made before 1 September 2014</li> <li>• CAC is issued by TGA on or after 1 June 2015</li> <li>• an effective application for inclusion in the Register is made within 30 days after CAC issued</li> <li>• the application is finally determined (i.e. is not granted, and there is no longer any possibility of a change in that outcome).</li> </ul>	The day the application for inclusion is finally determined.
11.8(7)	<ul style="list-style-type: none"> <li>• an effective application for CAC is made before 1 September 2014</li> <li>• CAC is issued on or after 1 June 2015</li> </ul>	30 days after the day CAC issued.

<sup>1</sup> Regulation 4.1 of the Principal Regulations sets out which IVDs are required to have a conformity assessment certificate issued before an application for their inclusion in the Register can be made. They include any IVDs manufactured in Australia (other than Class 1 IVDs and Class 1-3 in-house IVDs (see regulation 4.1(1) and (3)) and Class 4 IVDs and Class 4 in house IVDs (see regulation 4.1(2)(e)).

<sup>2</sup> Under subsection 41EB(2) of the Act, an effective application for a conformity assessment certificate is one that does not contain information that is false or misleading, and where the application fee has been paid.

<sup>3</sup> Under subsection 41FC(2) of the Act, an effective application for the inclusion of a kind of medical device in the Register is, principally, one that does not contain any information that is false or misleading, that utilises the approved form and where the prescribed application fee is paid.

New provision	Scenario	Transition day - when new framework applies
	<ul style="list-style-type: none"> <li>no effective application for inclusion in the Register is made within 30 days after CAC issued.</li> </ul>	
11.8(8)	<ul style="list-style-type: none"> <li>an effective application for CAC is made before 1 September 2014</li> <li>the application is finally determined (i.e. is not issued, and there is no longer any possibility of a change in that outcome).</li> </ul>	The day the application for the CAC is finally determined.
11.9	<ul style="list-style-type: none"> <li>no effective CAC application is made before 1 September 2014.</li> </ul>	1 September 2014.
Where CAC not required before an application can be made for inclusion of the device in the Register as a medical device:		
11.10(2)	<ul style="list-style-type: none"> <li>an effective application for inclusion in the Register is made before 1 July 2015</li> <li>device is included in the Register.</li> </ul>	The day the device is included in the Register.
11.10(3)	<ul style="list-style-type: none"> <li>an effective application for inclusion in the Register is made before 1 July 2015</li> <li>the application is finally determined (i.e. is not granted, and there is no longer any possibility of a change in that outcome).</li> </ul>	The day the application for inclusion is finally determined.
11.10(4)	<ul style="list-style-type: none"> <li>no effective application for inclusion in the Register is made before 1 July 2015.</li> </ul>	1 July 2015.

The various transition days set out in the table above represent an extension of the current transition period for these devices, but the length of the extension depends on the particular circumstances.

IVDs for which a conformity assessment certificate is required to be in place before an application can be made to include them in the Register are:

- classes 2 and 3 commercial IVDs manufactured in Australia; and
- class 4 commercial IVDs (whether manufactured in Australia or overseas) and class 4 in-house IVDs (these are, by their nature, only manufactured in Australia).

Under regulation 11.11, once a transitional device that is a listed or registered therapeutic device has reached its transition day, its registration or listing is taken to be cancelled – this represents a continuation of the current approach in subregulation 5(3) of the 2010 MD Amendments.

#### **Subdivision D – Approved transitional devices**

This Subdivision applies to transitional devices that, immediately before 1 July 2010, were either approved under paragraph 19(1)(b) of the Act or exempt from the requirement to be registered or listed as therapeutic devices due to use in a clinical trial, or were the subject of an application for such an approval which had not been finally determined at that date.

Regulation 11.13 introduces an equivalent amendment to regulation 11.7 above, by applying the new IVD framework for such IVDs for the purposes of applying for, or being issued, a conformity assessment certificate or applying for inclusion, or being included, in the Register. Regulation 11.14 sets out that the transition day for approved transitional devices is when, for instance, the clinical trial in relation to which they were approved or exempt, ceases.

The exception to this is an approved transitional device that, immediately before 1 July 2010, was the subject of an application for an approval under paragraph 19(1)(b) of the Act for use in a clinical trial that had not been finally determined. Under paragraph 11.14(c)(ii), the transition day for such IVDs is the day that application is finally determined, that is the day on which, the approval having been rejected, there is no longer any possibility of a change in that outcome.

Subdivision D represents an extension of the current transitional arrangements in regulation 5(5) of the 2010 MD Amendments for IVDs defined in Subdivision 11.1 as approved transitional devices.

#### **Subdivision E – Class 4 in-house IVD medical devices**

This Subdivision applies to Class 4 in-house IVDs, irrespective of when they come into existence.

Regulation 11.16 introduces an equivalent amendment to regulations 11.7 and 11.13 above, by applying the new IVD framework for such IVDs for the purposes of applying for, or being issued, a conformity assessment certificate or applying for inclusion, or being included, in the Register.

Regulations 11.17-11.19 set out when Class 4 in-house IVDs are subject to the new framework for all purposes, depending on the particular circumstances applying in relation to the device.

**Table 2** lists each of these circumstances, identifying when each device are subject to the new framework.

**Table 2**

<b>New provision</b>	<b>Scenario</b>	<b>Transition day - when new framework applies</b>
Where a Class 4 in-house IVD exists before 1 July 2016:		
11.17(2)	<ul style="list-style-type: none"> <li>• an effective application for CAC is made before 1 July 2016</li> <li>• CAC is issued by TGA before 1 June 2017</li> <li>• an effective application for inclusion in the Register is made before 1 July 2017</li> <li>• the device is included in the Register.</li> </ul>	The day the device is included in the Register.
11.17(3)	<ul style="list-style-type: none"> <li>• an effective application for CAC is made before 1 July 2016</li> <li>• CAC is issued by TGA before 1 June 2017</li> <li>• an effective application for inclusion in the Register is made before 1 July 2017</li> <li>• the application is finally determined (i.e. is not granted, and there is no longer any possibility of a change in that outcome).</li> </ul>	The day the application for inclusion is finally determined.
11.17(4)	<ul style="list-style-type: none"> <li>• an effective application for CAC is made before 1 July 2016</li> <li>• CAC is issued by TGA before 1 June 2017</li> <li>• no effective application for inclusion in the</li> </ul>	1 July 2017.

New provision	Scenario	Transition day - when new framework applies
	Register is made before 1 July 2017.	
11.17(5)	<ul style="list-style-type: none"> <li>• an effective application for CAC is made before 1 July 2016</li> <li>• CAC is issued by TGA on or after 1 July 2017</li> <li>• an effective application for inclusion in the Register is made within 30 days after CAC issued</li> <li>• the device is included in the Register.</li> </ul>	The day the device is included in the Register.
11.17(6)	<ul style="list-style-type: none"> <li>• an effective application for CAC is made before 1 July 2016</li> <li>• CAC is issued by TGA on or after 1 July 2017</li> <li>• an effective application for inclusion in the Register is made within 30 days after CAC issued</li> <li>• the application is finally determined (i.e. is not granted, and there is no longer any possibility of a change in that outcome).</li> </ul>	The day the application for inclusion is finally determined.
11.17(7)	<ul style="list-style-type: none"> <li>• an effective application for CAC is made before 1 July 2016</li> <li>• CAC is issued by TGA on or after 1 July 2017</li> <li>• no effective application for inclusion in the Register is made within 30 days after CAC issued.</li> </ul>	30 days after the day CAC issued.
11.17(8)	<ul style="list-style-type: none"> <li>• an effective application for CAC is made before 1 July 2016</li> <li>• an application for CAC is finally determined (i.e. is not issued, and there is no longer any possibility of a change in that outcome).</li> </ul>	The day the application for the CAC is finally determined.
11.18	<ul style="list-style-type: none"> <li>• no effective application for a CAC is made before 1 July 2016.</li> </ul>	1 July 2016
Where Class 4 in-house IVD comes into existence on or after 1 July 2016:		
11.19	<ul style="list-style-type: none"> <li>• comes into existence on or after 1 July 2016.</li> </ul>	On and after the day the device comes into existence.

The various transition days set out in the table above represent an extension of the current transition period for Class 4 in-house IVDs, but the length of the extension depends on the particular circumstances.

A conformity assessment certificate is required for all Class 4 IVDs (whether commercial or in-house) before they can be the subject of an application for inclusion in the Register.

### **Subdivision F – Class 1, 2 and 3 in-house IVD medical devices**

This Subdivision applies to Class 1-3 in-house IVDs irrespective of when they come into existence.

These IVDs are not required under regulation 4.1 of the Principal Regulations to have a conformity assessment certificate issued. Regulation 11.21 has the effect that the new IVD framework applies to Class 1-3 in-house IVDs from the later of 1 July 2017 and when the device comes into existence. Manufacturers of such devices in existence before 1 July 2017 therefore has until (i.e. up to and including) 30 June 2017 to comply with the requirements of the new framework.

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

This is a new heading to be inserted at the end of Division 11.1 in the Principal Regulations.

**Item 3 – Regulation 11.1**

This item makes a change to the numbering of an existing regulation to reflect the introduction of new Division 11.1 by item 2.

**Part 2 – Other amendments**

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

This item makes a minor, consequential amendment to subclause 1.2(1) of the Principal Regulations (which requires manufacturers of Class 1-3 in-house IVDs to notify the Secretary of the Department of Health of their contact details and the IVDs they manufacture) by replacing the reference to 1 July 2014 in that subclause to 1 July 2017. This reflects that the amendments in regulation 11.21 above (which include the application of Part 6A of Schedule 3 to the Principal Regulations to the in-house IVD) only applies the new IVD framework to Class 1-3 in-house IVDs from 1 July 2017.

## Schedule 2 – Amendments of the Therapeutic Goods Regulations 1990

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

#### **Item 1 – Before regulation 49 (new Division 1 – Transitional provisions relating to the Therapeutic Goods Amendment Regulations 2010 (No.1))**

##### ***Summary of changes in item***

This item introduces a new Division 1 to replace, from 1 July 2014, the current transitional arrangements for IVDs that are set out in the *Therapeutic Goods Amendment Regulations 2010 (No. 1)* (the 2010 TG Amendments), with new transitional arrangements (Schedule 3 to this regulation repeals the 2010 TG Amendments from the last moment in time on 30 June 2014 to ensure a seamless changeover from the current to the revised arrangements).

When, on 1 July 2010, amendments to the *Therapeutic Goods (Medical Devices) Regulations 2002* introduced a new regulatory framework for IVDs, consequential amendments were also made to the *Therapeutic Goods Regulations 1990* to support the introduction of the new framework (see Schedule 1 to the 2010 TG Amendments).

The effect of the amendments in Schedule 1 to the 2010 TG Amendments was to remove the references to IVDs in the *Therapeutic Goods Regulations 1990* as they were immediately before 1 July 2010. However, under the transitional arrangements in the 2010 TG Amendments (regulations 4, 5, 6 and 7), those amendments do not come into operation for an IVD until the new IVD framework (as set out in Schedule 1 to the *Therapeutic Goods (Medical Devices) Amendment Regulations 2010 (No. 1)* (the 2010 MD amendments)) applied to them. In so doing, the transitional arrangements in the 2010 TG Amendments were designed to mirror the effect of the transitionals provisions (regulations 4, 5, 6 and 7) in the 2010 MD amendments.

As soon as the transitional provisions in the 2010 MD Amendments had the effect of applying Schedule 1 to the 2010 MD Amendments to the IVD in question for all purposes, then the amendments in Schedule 1 to the 2010 TG Amendments also apply to the IVD in question.

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

This Division defines a number of key terms, for example, ‘transitional device’, ‘transition day’ and ‘finally determined’. New regulation 48A gives each of these terms the same meaning as in the amendments to the *Therapeutic Goods (Medical Devices) Regulations 2002* in Schedule 1 above.

The Division also includes a new regulation 48B in the *Therapeutic Goods Regulations 1990* which applies the amendments made by Schedule 1 to the 2010 TG Amendments to a transitional device on and after the transition day for the device. In other words, this is the same day as the day that, under the provisions in Schedule 1 above, the new IVD framework (set out in Schedule 1 to the 2010 MD Amendments) applies to the device.

New regulation 48B also makes clear that the amendments made by the 2010 TG Amendments apply in relation to transitional devices that are excluded from the operation of new Division 11.1 of the *Therapeutic Goods (Medical Devices) Regulations 2002* inserted by Schedule 1 above (i.e. those already included in the Register under Chapter 4 of the Act or in

relation to which a decision to reject their inclusion in the Register has been finally determined).

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

This is a new heading to be inserted before regulation 49 in the *Therapeutic Goods Regulations 1990*.

**Item 2 – Regulation 49**

This item makes a minor correction to include the missing number in the title of the amending instrument, the *Therapeutic Goods Amendment Regulation 2012 (No. 3)*.

### Schedule 3 – Repeals

#### **Items 1 and 2 – Repeal of 2010 regulations**

Items 1 and 2 repeals, from the end of the day on 30 June 2014, the *Therapeutic Goods (Medical Devices) Amendment Regulations 2010 (No. 1)* (the 2010 MD Amendments) and the *Therapeutic Goods Amendment Regulations 2010 (No. 1)* (the 2010 TG Amendments).

As the amendments in Schedules 1 and 2 of the regulations above extend the previous transitional arrangements set out in the 2010 MD Amendments and in the 2010 TG Amendments from 1 July 2014, it is no longer necessary for them to continue.

The repeal operates from the end of the day on 30 June 2014 to ensure that there is no overlap of those 2010 amendments with these new amendments to the *Therapeutic Goods (Medical Devices) Regulations 2002* (in Schedule 1 above) and the *Therapeutic Goods Regulations 1990* (in Schedule 2 above). The effect is that the transitional devices that were not included in the Register under Chapter 4 of the Act between 1 July 2010 and 30 June 2014 or in relation to which a decision to reject an application for inclusion in the Register was finally determined during that period, are covered by the amendments made by Division 11.1 of Part 11 of the *Therapeutic Goods (Medical Devices) Regulations 2002* and Division 1 of Part 9 of the *Therapeutic Goods Regulations 1990*.



## Statement of Compatibility with Human Rights

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

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

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

#### **Overview of the Legislative Instrument**

The *Therapeutic Goods Legislation Amendment (In Vitro Diagnostic Medical Devices) Regulation 2014* (the Amendment Regulation) is made under subsection 63(1) of the *Therapeutic Goods Act 1989* (the Act). In vitro diagnostic medical devices (IVDs) are medical devices intended by their manufacturer to be used in vitro (i.e. “in glass”) for the examination of specimens from the human body. Typically, they are commercial products or tests that have been developed ‘in-house’ by a laboratory.

On 1 July 2010 a new, tailored framework for IVDs was introduced through amendments to the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Principal Regulations), under which these products are regulated as medical devices under Chapter 4 of the Act (previously they had been regulated as therapeutic devices under Part 3-2 of the Act). At the same time, amendments were also made to the *Therapeutic Goods Regulations 1990* (the TG Regulations), consequential on the introduction of the new framework. IVDs in existence immediately before 1 July 2010, and in-house IVDs coming into existence between 1 July 2010 and 30 June 2014, were given up to 30 June 2014 to transition to the new framework.

It has become apparent that there is a need for additional time to assist sponsors and manufacturers of IVDs to successfully migrate to the new framework, including for manufacturers to compile the full range of documentation needed to support the safety and performance of their devices.

The purpose of the Amendment Regulation is to amend the Principal Regulations to extend the current transitional arrangements for IVDs (with some minor changes), with special provisions for IVDs for which, under the Act, a conformity assessment certificate is required to be issued by the Therapeutic Goods Administration (TGA) before an application for marketing approval for the IVD can be made to the TGA. The Amendment Regulation also makes a small number of amendments to the TG Regulations consequential on that extension.

#### **Human rights implications**

As the Amendment Regulation does not introduce any changes to the Principal Regulations other than to implement the change mentioned above, it does not engage any of the applicable rights or freedoms.

#### **Conclusion**

This legislative instrument is compatible with human rights as it does not raise any human rights issues.

**Fiona Nash**

**Assistant Minister for Health**