

EXPLANATORY STATEMENT

Select Legislative Instrument No. 188, 2015

Therapeutic Goods Act 1989

Therapeutic Goods (Medical Devices) Amendment (In Vitro Diagnostic Medical Devices) Regulation 2015

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 used in, or exported from, Australia. The Therapeutic Goods Administration, a 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') to examine specimens derived from the human body – generally, these are pathology tests and related instrumentation for testing human samples, where the results are intended to assist in clinical diagnosis and management. Typically used in diagnostic laboratories, at the point of care and in the home, IVDs can be commercially manufactured products or developed “in-house” by a laboratory, including through the adaptation of a commercial IVD.

On 1 July 2010 a new, tailored, regulatory framework for IVDs was introduced. Under this 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) or exempt from registration or listing and some were approved for limited uses (e.g. clinical trials).

Under transitional provisions in the Therapeutic Goods (Medical Devices) Amendment Regulations 2010 (No.1), IVDs in existence immediately before 1 July 2010 were given until 30 June 2014 to transition to the new framework. 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.

These deadlines were extended in 2014 by amendments to the Therapeutic Goods (Medical Devices) Regulations 2002 (the Principal Regulations), to 30 June 2015 for commercial IVDs and to 30 June 2017 for in-house IVDs, in recognition that more time was needed to assist sponsors and manufacturers of IVDs to migrate successfully to the new framework.

In recent times, concerns have arisen that manufacturers of in-house IVDs are experiencing, or are expected to experience, difficulties in complying with the new regulatory framework, and in relation to meeting the costs associated with that compliance. In particular, the new framework requires manufacturers of Class 4 in-house IVDs to comply with the same conformity assessment procedures as commercial Class 4 IVDs, and requires Class 4 in-house IVD manufacturers to obtain a conformity assessment certificate before a valid application can be made to include their devices in the Register (this is also the case for Class 4 commercial IVDs).

Conformity assessment procedures set out standards for the manufacture of medical devices, and require that the manufacturing process meets specified benchmarks for ensuring the safety and performance of the devices being manufactured, and for ensuring that devices are manufactured in accordance with their specifications.

The current conformity assessment procedures for Class 4 IVDs are not always appropriate for in-house IVDs. For example, in Australia there is currently a lack of suitable commercial serology IVDs to screen both living and deceased donors for infectious diseases including supplementary donor screening for diseases, such as malaria. Some laboratories have adapted commercial IVDs for these purposes, but those laboratories may be unable to comply with the current procedures for Class 4 IVDs because they have no control over the design and manufacturing processes for the commercial products so adapted.

There are concerns that if laboratories are not able to comply with the IVD regulatory framework, there may be a threat to the continued availability of important services such as donor screening of blood, organs and other biological products.

The purpose of the Therapeutic Goods (Medical Devices) Amendment (In Vitro Diagnostic Medical Devices) Regulation 2015 (the Regulation) is therefore to amend the Principal Regulations to better tailor the IVD framework for in-house IVDs -including introducing alternative specific conformity assessment procedures for Class 4 in-house IVDs. The alternative procedures in particular allow laboratories to rely on accreditation by the National Association of Testing Authorities as complying with *ISO 15189 Medical laboratories- Requirements for quality and competence* – something most laboratories would already meet for other reasons, e.g. ensuring that certain pathology tests they do qualify for Medicare rebates. Laboratories manufacturing blood, blood components, plasma derivatives, or human cell or tissue products will also be able to rely on their manufacturing licence issued under the Act – again, this is something they would already be required to hold in order to manufacture such products.

The changes provide appropriate flexibility for Class 4 in-house IVDs and ensure the continued availability of critical laboratory testing in Australia needed for a range of important services, such as donor screening. The Regulation also amends the conformity assessment procedures for Class 1-3 in-house IVDs to provided additional flexibility in terms of the international standards that must be observed in the manufacturing process, and make a minor adjustment to the classification rules for Class 3 IVDs.

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*.

The Regulation commences on the day after it is registered.

Consultation

The TGA undertook extensive consultation with stakeholders – laboratories, industry, consumers and peak bodies and individuals associated with the IVD sector - between 2013 and 2014 to address several issues relating to the regulation of IVDs. The consultation included the amendments made in 2014 to extend the transitional period as mentioned above, as well as the need to provide for additional flexibility for in-house IVDs in complying with conformity assessment requirements under the new framework as now proposed. A consultation paper sought submissions in 2013 (to which 34 submissions were received), and this process was followed by numerous face to face meetings with stakeholders. A Regulation Impact Statement was also prepared and published on TGA’s website in October 2014. The majority of stakeholders recognised the need for changes to the conformity assessment requirements for in-house IVDs and supported the proposed measures, with laboratories in particular welcoming the proposals.

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

Details of the *Therapeutic Goods (Medical Devices) Amendment (In Vitro Diagnostic Medical Devices) Regulation 2015***Section 1 – Name of regulation**

This section provides for the Regulation to be referred to as the *Therapeutic Goods (Medical Devices) Amendment (In Vitro Diagnostic Medical Devices) Regulation 2015*.

Section 2 – Commencement

This section provides for the Regulation to commence on the day after it is registered.

Section 3 – Authority

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

Section 4 – Schedule

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 – Amendments related to Class 4 in-house IVD medical devices*****Therapeutic Goods (Medical Devices) Regulations 2002*****Items 1 and 2 – Regulation 3.6A**

Regulation 3.6A of the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Principal Regulations) specifies the conformity assessment procedures that must be observed in the manufacturing process for Class 4 in-house IVDs – currently, it covers both commercial Class 4 IVDs and Class 4 in-house IVDs.

Conformity assessment procedures set out standards for the manufacture of medical devices, and principally require that the manufacturing process meets specified benchmarks for ensuring the safety and performance of the devices being manufactured.

Sponsors of medical devices, including IVDs, must certify that an appropriate conformity assessment procedure has been applied to their devices when they apply for the inclusion of their devices in the Australian Register of Therapeutic Goods (the Register). Criminal offences may also apply under the Act for supplying or exporting medical devices to which conformity assessment procedures have not been applied.

The procedures referred to in regulation 3.6A are either the full quality assurance procedures (set out in Part 1 of Schedule 3 to the Principal Regulations), or the type examination procedures and the production quality assurance procedures (set out, respectively, in Parts 2 and 4 of Schedule 3 to the Principal Regulations).

As item 3 introduces a new regulation 3.6B giving manufacturers of Class 4 in-house IVDs the option of complying with new, in-house IVD-specific conformity assessment procedures,

items 1 and 2 make consequential amendments to regulation 3.6A to make it clear that it will only apply to commercial Class 4 IVDs, and not to Class 4 in-house IVDs.

Item 3 – After regulation 3.6A

Item 3 includes a new regulation 3.6B to Division 3.2 of the Principal Regulations, which specifies the conformity assessment procedures that apply in relation to the manufacturing of Class 4 in-house IVDs.

The effect of new Regulation 3.6B is to give laboratories manufacturing Class 4 in-house IVDs the option of either applying the current full quality assurance procedures (set out in Part 1 of Schedule 3 to the Principal Regulations) or a new set of procedures, specifically designed for Class 4 in-house IVDs, which are set out in new Part 6B of Schedule 3 (item 9 refers).

Item 4 – Paragraph 4(1)(e)

Under paragraph 4(1)(e) of the Principal Regulations, manufacturers of all Class 4 in-house IVDs are required to apply to the Secretary of the Department of Health for, and be issued, a conformity assessment certificate before a valid application can be made to include the device in the Australian Register of Therapeutic Goods (the Register).

Item 4 amends paragraph 4(1)(e) to remove this requirement for conformity assessment certificates to be in place for all Class 4 in-house IVDs with a new requirement that, in relation to Class 4 in-house IVDs, a certificate will only be needed for those Class 4 in-house IVDs to which the full quality assurance procedures in Part 1 of Schedule 3 have been applied.

This has the effect that laboratories manufacturing Class 4 in-house IVDs who opt, under new regulation 3.6B (item 3 refers), to apply the new in-house-specific conformity assessment procedures introduced by this Regulation to their devices (item 9 refers), will not need a conformity assessment certificate before they can apply to include their devices in the Register.

Conformity assessment certificates signify a range of matters about the manufacture of the medical devices to which they relate, e.g. that they comply with minimum requirements for performance and safety, and that relevant manufacturing standards are being observed in the manufacturing process.

Item 5 – At the end of paragraph 5(3)(1)(j)

Subregulation 5.3(1) of the Principal Regulations lists, for the purposes of section 41FH of the Act, medical devices in relation to which the Secretary must conduct an audit of any application for inclusion of a kind of medical device in the Register.

An application audit can involve a review of a manufacturer's technical documentation provided with an application for marketing approval, to assess compliance with the essential principles (these are minimum requirements for performance and safety for medical devices), conformity assessment procedures and other relevant requirements of the legislation, for example with regards to any proposed advertising of the device.

Item 5 amends subregulation 5.3(1) to refer to Class 4 in-house IVDs. The effect of this is that the only applications for inclusion in the Register for Class 4 in-house IVDs that will require an application audit will be those involving Class 4 in-house IVDs to which the

laboratory has opted to apply the new conformity assessment procedures for Class 4 in-house IVDs in new Part 6B of Schedule 3 to the Principal Regulations.

It will be important that an audit is undertaken for these IVDs, as they would not have been previously examined for safety or performance because a conformity assessment certificate would not be required for such products.

Item 6 – Paragraph 9.7(1)(d)

Regulation 9.7 of the Principal Regulations allows the Secretary to reduce assessment fees in relation to application audits for a number of specified kinds of medical devices, if the Secretary already has information that allows the assessment to be abridged.

Item 11 introduces two new application audit assessment fees for Class 4 in-house IVDs (one for Class 4 in-house IVDs that are immunohaematology reagents and one for all other Class 4 in-house IVDs), and item 6 has the effect of allowing the Secretary to reduce those fees if the Secretary has information that would allow the assessments to be done more quickly.

Items 7 and 8 – Part 4 of Schedule 3

Items 7 and 8 make minor, consequential amendments to Part 4 of Schedule 3 to the Principal Regulations to remove references to Class 4 in-house IVDs, to reflect the changes introduced by items 1-3 above.

Currently, regulation 3.6A of the Principal Regulations prescribes the conformity assessment procedures that must be applied to all Class 4 IVDs, both commercial and in-house, and gives manufacturers the option of applying the full quality assurance procedures in Part 1 of Schedule 3, or the type examination procedures and production quality assurance procedures in Part 4 of Schedule 3.

As items 1 and 2 limit regulation 3.6A to only commercial Class 4 IVDs, and as item 3 introduces a new 3.6B prescribing conformity assurance procedures specifically for Class 4 in-house IVDs (which do not include they type examination or production quality assurance procedures in Part 4 of Schedule 3) the references to Class 4 in-house IVDs in Part 4 of Schedule 3 is now redundant.

Item 9 – new Part 6B of Schedule 3 – Procedures applying to Class 4 in-house IVDs

Item 9 introduces a new Part 6B to Schedule 3 to the Principal Regulations, which sets out new conformity assessment procedures specifically designed for Class 4 in-house IVDs.

Under new regulation 3.6B, laboratories manufacturing Class 4 in-house IVDs have the option of applying these new procedures to their devices, as an alternative to the existing full quality assurance procedures in Part 1 of Schedule 3.

These new procedures include requirements for laboratories manufacturing Class 4 in-house IVDs in relation to:

- implementing a quality management system to ensure the manufacturing process supports the safety and performance of the kind of devices being manufactured;
- preparing, and having available, technical documentation in relation to the kinds of devices being manufactured;
- establishing and maintaining a post-market monitoring system;

- making a declaration of conformity about the application of the conformity assessment procedures in proposed new Part 6B to the manufacturer's devices; and
- maintaining relevant records in relation to the application of those procedures.

Quality management system

In relation to the requirement to have a quality management system in place, subregulation 6B.3 gives laboratories that also undertake steps of manufacture of blood, blood components, plasma derivatives and human cell and tissue based goods the option of either:

- satisfying the *Australian Code of Good Manufacturing Practice for Blood and Blood Components, Human Tissues and Human Cellular Therapy Products* published by TGA (the GMP Code), as amended from time to time, and holding a manufacturing licence issued under Part 3-3 of the Act that is in force and that authorises the manufacture of the relevant blood etc. product; or
- being accredited by the National Association of Testing Authorities (NATA) as complying with *ISO 15189 Medical laboratories-Requirements for quality and competence* (ISO 15189), as amended from time to time and meeting the National Pathology Accreditation Advisory Council (NPAAC) standard *Requirements for the Development and Use of in-house In Vitro Diagnostic Devices*, as amended from time to time.

These options reflect the fact that that some laboratories (principally, those engaged in donor screening of blood and blood products) would already have a manufacturing licence issued under Part 3-3 of the Act in relation to their manufacture of such products, and would be required to comply with the GMP Code as a condition of that licence. However, other laboratories (for example, those engaged in the donor screening of organs) may not have a manufacturing licence. The new procedures therefore give such laboratories the option of utilising NATA/NPAAC accreditation instead. Laboratories not involved in the manufacture of blood, blood components, plasma derivatives or human cell and tissue goods will need to have the NATA/NPAAC accreditation noted above.

These laboratories would already maintain NATA//NPAAC compliance for other reasons, so such a requirement represents a reduction in regulatory burden compared with the current Class 4 IVD procedures. For example, NATA, in conjunction with the Royal College of Pathologists of Australasia (RCPA), currently accredits laboratories testing in various fields of human pathology, e.g. microbiology and immunology. Medicare rebates for such tests are only available to laboratories that hold this accreditation.

Technical documentation

New subregulation 6B.4 requires laboratories manufacturing Class 4 in-house IVDs to maintain, and have available to provide to the Secretary if requested, a range of technical documentation in relation to the kinds of devices being manufactured.

This includes, for example, documentation relating to the details of the manufacturing processes and the systems used for ensuring that the kind of device complies with the essential principles, a description of the device and details of its design specification.

Post-market monitoring system

New subregulation 6B.5 requires laboratories manufacturing Class 4 in-house IVDs to have and maintain a system for monitoring the safety and performance of the devices they are manufacturing. This includes, for example, having the means to implement any necessary

corrective action in relation to the design or production of their devices, and notifying the Secretary as soon as practicable after becoming aware of information that might lead to the death or serious deterioration of the health of a patient or user or the device.

Declaration of conformity

New subregulation 6B.6 requires laboratories manufacturing Class 4 in-house IVDs to make a declaration of conformity in relation to each kind of device manufactured.

This includes, for example, stating that the kind of device satisfies the requirements of the GMP Code or NATA/NPAAC and providing the relevant manufacturing licence number or NATA accreditation number for a kind of device used in the manufacture of blood, blood products etc., or satisfies the requirements of NATA/NPAAC and providing the NATA accreditation number for a kind of device not involved in such manufacture, stating that the kind of device complies with the essential principles and stating that the classification rules for medical devices in the Principal Regulations and the conformity assessment procedures in new Part 6B have been applied to the kind of device.

Records

New subregulation 6B.7 requires laboratories manufacturing Class 4 in-house IVDs to keep records relating to a range of matters in relation to their devices, for at least 5 years after ceasing to manufacture each kind of device. This includes, for example, records relating to the technical documentation referred to in new subregulation 6B.4, details of any changes made to the kinds of devices manufactured and the declaration of conformity required under subregulation 6B.6.

Item 10 – Part 1 of Schedule 5 (after table item 1.14A)

As noted above, item 5 amends subregulation 5.3(1) of the Principal Regulations to refer to Class 4 in-house IVDs (with the effect that applications for inclusion in the Register of Class 4 in-house IVDs to which the manufacturer has opted to apply the conformity assessment procedures in new Part 6B of Schedule 3 would require an application audit).

Item 10 introduces two application audit fees for Class 4 in-house IVDs required to undergo an application audit – these are a fee for Class 4 in-house IVDs that are an immunohaematology reagent IVD, and a fee for other Class 4 in-house IVDs.

Part 2 – Amendments relating to Class 1, 2 and 3 in-house IVD medical devices

Therapeutic Goods (Medical Devices) Regulations 2002

Item 11 – Part 6A of Schedule 3 (heading)

This item replaces the current heading of Part 6A of Schedule 3 to the Principal Regulations with a new heading making it clearer that Part 6A sets out conformity assessment procedures for Class 1, 2 and 3 in-house IVDs.

Item 12 – Clauses 1.1 and 1.2 of Part 6A of Schedule 3

Item 12 repeals current clauses 1.1 (Overview) and 1.2 (Procedures) of Part 6A of Schedule 3 with new, renumbered clauses 6A.1 and 6A.2.

The new clause 6A.1 provides more of a general overview of the procedures in Part 6A than current clause 1.1, which simply states that Part 6A applies to Class 1- 3 in-house IVDs.

The new clause 6A.2 replaces the current requirement in clause 1.2 that laboratories notify the Secretary of their address and the details of all the Class 1, 2 or 3 in-house IVDs they are manufacturing by 1 July 2017 and annually after that, with a new requirement for such information to be provided on, or within 20 working days of, 1 July 2017 – in relation to those devices that are in existence at that time.

Laboratories that do not comply with this requirement, within the timeframe of 20 working days after 1 July 2017 would then be at risk of the offence provisions in Division 2 of Part 4-11 of the Act, which set out criminal offences and civil penalty provisions in relation to supplying medical devices to which applicable conformity assessment procedures have not been applied.

For devices manufactured for the first time after 1 July 2017, or devices not covered by a laboratory's most recent such notification, laboratories would be required to notify the Secretary of those (and the details of all the other IVDs they are still manufacturing at that time that have previously been notified) by 1 July of the following financial year, or within 20 working days, whichever is the later.

The application provisions (item 47 refers) set out arrangements for those laboratories that have already notified the Secretary of their devices in accordance with the current clause 1.2 before this Amendment Regulation commences, and for those laboratories that notify the Secretary between that commencement and 1 July 2017.

The other main effect of item 12 is to provide additional flexibility for laboratories manufacturing Class 1, 2 or 3 in-house IVDs in relation to the international standards that must be observed as part of their conformity assessment procedures.

Currently under subclause 1.2(4) of Part 6A, these laboratories must comply with ISO 15189. New subclause 6A.2(3), however, would provide an alternative option of meeting *ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories* (ISO 17025) instead.

This will particularly benefit non-medical testing laboratories, such as public health and animal health laboratories, which manufacture critical Class 1-3 in-house IVDs – e.g. Class 3 in-house IVDs used by animal and public health laboratories to detect Rabies (Lyssavirus) and Hendra virus - and that are currently accredited by NATA in relation to ISO 17025 rather than ISO 15189. Medical testing laboratories will still require NATA accreditation to ISO 15189, as without this they would be unable to access Medicare rebates.

Items 14 and 15 – Clause 1.3 of Part 6A of Schedule 3

Item 14 makes minor changes to clause 1.3 of Part 6A of Schedule 3 to renumber that clause as clause 6A.3, and to substitute a new heading that would correct an error. The existing heading refers to the provision of information to an authorised person - this is incorrect as clause 1.3 requires laboratories to provide information to the Secretary, if asked to do so by an authorised person.

Current subclause 1.3(1) requires a laboratory that manufactures a Class 1, 2 or 3 in-house IVD to provide the information listed in paragraphs 1.3(1)(a) and (b) to the Secretary, if asked to do so by an authorised person, but does not specify a timeframe for a laboratory to comply with such a request.

Item 15 addresses this by replace the current subclause 1.3(1) with a new subclause 6A.3(1), the main effect of which would be to specify a period of 20 working days for a laboratory to provide the requested information to the Secretary.

Items 16, 17, 19 21 and 22

Clause 1.3 of Part 6A of Schedule 3 (which set out requirements for laboratories that manufacture of Class 1, 2 and 3 in-house IVDs for providing information to the Secretary about their processes and devices) currently includes a number of references to such products as “kinds of medical device”.

However, Class 1, 2 and 3 in-house IVDs are not “kinds of” medical devices as that term is defined in section 41BE of the Act, as they do not fulfil all of the criteria for that definition (principally because they do not necessarily have the same device nomenclature system code).

These items have the effect of replacing references in clauses 1.3 to “kind of medical device” with “device” to reflect that, and to make it clearer that the requirements in those clauses apply in relation to each of a laboratory’s Class 1, 2 or 3 in-house IVDs.

Item 18 – Subparagraph 1.3(2)(c)(ii) of Part 6A of Schedule 3

Subparagraph 1.3(2)(c)(ii) of Part 6A of Schedule 3 requires a laboratory manufacturing a Class 1, 2 or 3 in-house IVD to give to the Secretary (upon request by an authorised person), a general description of the kind of device, and of any variants the manufacturer plans to manufacture.

As noted above, the reference to “kind of” medical device in subparagraph 1.3(2)(c)(ii) is not accurate. In addition, however, it is not considered necessary to require laboratories to provide details of possible variant Class 1, 2 or 3 in-house IVDs that they are only planning to manufacture (as opposed to Class 1, 2 or 3 in-house IVDs that they are actually manufacturing).

Item 18 therefore amends subparagraph 1.3(2)(c)(ii) to remove the reference to “kind” and the requirement for laboratories to provide a description of planned variants.

Item 20 - Subparagraphs 1.3(2)(c)(iii)(A) and (C) of Part 6A of Schedule 3

Subparagraphs 1.3(2)(c)(iii)(A) and (C) of Part 6A of Schedule 3 require laboratories manufacturing Class 1,2 or 3 in-house IVDs to provide the Secretary with certain information relating to the design specifications of their products, including in particular whether any conformity assessment standards have been applied to the device.

Conformity assessment standards are non-mandatory standards made by the Minister under section 41DC of the Act, and the current such standards are not relevant to in-house IVDs.

Item 20 therefore removes the references to such standards in these 2 subparagraphs.

Item 23 – Paragraph 1.3(2)(f) of Part 6A of Schedule 3

Item 23 makes a minor editorial amendment to paragraph 1.3(2)(f) of Part 6A, as a consequence of the change proposed in item 24.

Item 24 – Subparagraph 1.3(2)(g) of Part 6A of Schedule 3

Paragraph 1.3(2)(g) of Part 6A of Schedule 3 requires laboratories manufacturing Class 1, 2 or 3 in-house IVDs to tell the Secretary if a conformity assessment standard has been applied to their quality management system or, if not, whether their system will ensure that each device they manufacture will comply with the essential principles, the classification rules for medical devices and the conformity assessment procedures set out in Part 6A.

As noted above, conformity assessment standards are non-mandatory standards made by the Minister under section 41DC of the Act, and the current such standards are not relevant to in-house IVDs. In addition, the requirement for the laboratory to provide information about their quality management system would seem to cover much of the same ground as existing paragraph 1.3(2)(c) of Part 6A.

Accordingly, paragraph 1.3(2)(g) is not necessary, and item 23 removes it.

Item 25 – Clause 1.4 of Part 6A of Schedule 3

Item 24 replaces clause 1.4 of Part 6A of Schedule 3 with a new, renumbered, clause 6A.4.

Principally, the new clause 6A.4 replaces references in clause 1.4 to “kind of medical device” with “device”, to reflect that Class 1, 2 and 3 in-house IVDs are not “kinds of” medical devices as that term is defined in section 41BE of the Act.

New clause 6A.4 also omits the current requirement in subparagraph 1.4(2)(c)(ii) that a laboratory that manufactures a Class 1, 2 or 3 in-house IVD notify the Secretary of any technical or medical reason for a malfunction or deterioration of the device that has led the laboratory to recover the device if it has been distributed. This requirement, however, is not relevant to in-house IVDs as these are only used within a laboratory or a laboratory network, and are not distributed commercially.

Items 26 - 29 – Part 2 of Schedule 4, table item 2.10

Item 2.10 of Part 2 of Schedule 4 to the Principal Regulations exempts Class 1, 2 and 3 in-house IVDs from the requirement to be included in the Register, provided they comply with the conditions specified in column 3 of the table in Part 2 of that Schedule.

Item 26 makes a very minor amendment to one of those conditions, at paragraph (b), to correct a typographical error.

Item 27 amends paragraph (c) of those conditions (which states that one of the requirements for Class 1, 2 or 3 in-house IVDs to be exempt from inclusion in the Register is that the manufacturer of the device must provide samples of the device to the Secretary, if asked to do so) to specify a timeframe for laboratories to comply with such a request. This is a period of 20 working days from the request for samples. Failure to comply with the request within the relevant period would mean the IVDs are not exempt from inclusion in the Register so it would be an offence under the Act to continue to supply them.

Item 28 makes an equivalent amendment to paragraph (d) of the item 2.10 conditions which requires laboratories to, upon request, give the Secretary information about whether their Class 1, 2 or 3 in-house IVD complies with the essential principles, conformity assessment procedures and any applicable advertising requirements. The period is also 20 working days from the request for the information. As noted above, failure to comply with the request

within the relevant period would mean the IVDs are not exempt from inclusion in the Register so it would be an offence under the Act to continue to supply them.

Item 29 substitutes a new subparagraph (f)(ii) of the item 2.10 conditions, to make a minor amendment to replace references to “kind of medical device” in that subparagraph with “device” to reflect that Class 1, 2 and 3 in-house IVDs are not “kinds of” medical devices as that term is defined in section 41BE of the Act.

Item 30 – Part 1 of Schedule 5, table item 1.17

Item 1.17 of Schedule 5 to the Principal Regulations is intended to specify a notification fee for the purposes of the current requirement at clause 1.2 of Part 6A of Schedule 3 for a laboratory manufacturing Class 1, 2 or 3 in-house IVDs to notify the Secretary on a day no later than 1 July 2017, and then annually after that time, of the devices they are manufacturing.

As set out above, new clause 6A.2 of Schedule 3 requires notification on or within 20 working days of 1 July 2017 for devices that are in existence at that time, and by 1 July of the following financial year, or within 20 working days, whichever is the longer, if a laboratory develops a new device after 1 July 2017 (item 12 refers).

Item 30 therefore substitutes a new item 1.17 that reflects these changes, and also make it clearer that item 1.17 applies in relation to Class 1, 2 or 3 in-house IVDs.

Part 3 – Other amendments

Therapeutic Goods (Medical Devices) Regulations 2002

Items 31 - 33 – Subclauses 1.3(1) and 1.3(2) of Schedule 2A, and item 1.5 of Schedule 5

Item 31 makes a minor, editorial amendment to subclause 1.3(1) of Schedule 2A to the Principal Regulations, to accommodate the changes proposed by item 32.

Item 32 amends one of the classification rules for IVDs (both commercial and in-house) which are set out in Schedule 2A.

Under subclause 1.3(2) of Schedule 2A, an IVD is classified as a Class 3 IVD or a Class 3 in-house IVD (as the case may be) if it is used to test for transmissible agents included in the Australian National Notifiable Diseases Surveillance System (NNDSS) list, as published from time to time by the Australian Government.

This list is maintained by the Department of Health, with the advice of the Communicable Diseases Network Australia (CDNA), a sub-committee of the Australian Health Protection Principal Committee, and includes for example diseases such as severe acute respiratory syndrome (SARS) and diphtheria. Considerations relating to the appropriate classification of the IVDs that are used to test specimens for these diseases are not relevant to, and are not included as part of, the process of determining whether diseases are included in the NNDSS list.

Determining the classification of IVDs on the basis of whether they test for diseases included in the NNDSS list may lead to the unintended consequence of some IVDs changing classification as a result of changes to the NNDSS list. This approach also does not align with the IVD classification rules proposed by the Global Harmonisation Task Force (GHTF), is

not consistent with other regulatory jurisdictions such as Canada, and it is no longer considered necessary to classify IVDs on this basis.

Item 32 therefore removes subclause 1.3(2) from Schedule 2A.

Removing the classification rule in subclause 1.3(2) means that the classification of IVDs that would otherwise have been covered by subclause 1.3(2) would be determined on the basis of the other classification rules in Schedule 2A.

The majority of the IVDs used to detect the transmissible agents on the NNDSS list that are currently covered by subclause 1.3(2) would also be covered by the classification rules in subclause 1.3(1). Subclause 1.3(1) states that an IVD will be a Class 3 IVD or a Class 3 in-house IVD (as the case may be) if it is used for any of the purposes specified at paragraphs 1.3(1)(a)-(j). These include, for example, detecting the presence of an infectious agent, if there is a significant risk that an erroneous result would cause death or severe disability to the individual or foetus being tested (1.3(1)(c)), and the management of patients suffering from a life-threatening infectious disease (1.3(1)(i)). It follows that in the majority of cases the IVDs that are affected by the removal of subclause 1.3(2) will continue to be classified as Class 3 devices.

In a small number of cases, affected IVDs may not otherwise be Class 3 devices following the removal of subclause 1.3(2), and will then be classified as Class 2. For IVDs that are affected in this way that are not in-house IVDs, sponsors will need to submit a new application for the inclusion of their devices in the Register, which the TGA would prioritise and expedite.

To assist in ensuring that affected sponsors are not inconvenienced, item 33 amends the application fee for the inclusion of IVDs in the Register, at paragraph 1.5(f) of Schedule 5 to the Principal Regulations, to ensure no application fee is payable for an application to include in the Register a Class 2 IVD that was, immediately before the commencement of this Amendment Regulation, classified as a Class 3 IVD on the basis of subclause 1.3(2) of Schedule 2A.

Item 34 includes a note under paragraph 1.5(f) of Schedule 5 explaining that no fee is payable in such circumstances.

Item 35 – 39 Amendments to Dictionary

Items 35-38 make a small number of minor changes to definitions in the Dictionary of the Principal Regulations to clarify the nature of laboratories and laboratory networks in which in-house IVDs may be used.

The Principal Regulations' Dictionary defines an in-house IVD as an IVD that stays within the confines or scope of an Australian medical laboratory or an Australian medical laboratory network, and that meets one of the descriptions in paragraphs (a)(i)-(iv) of that definition.

However, not all in-house IVDs are used in “medical” laboratories or laboratory networks (for example, some may be used in public health laboratories) and it was not intended that the scope of this term exclude products that are used in such settings.

Accordingly, items 35 and 36 remove references to “medical” in the definition of “in-house IVD”, and items 37 and 38 replace the current definition of “medical laboratory network”

with a new definition of “laboratory network” that does not include the reference to “medical” in that term.

The new definition of “laboratory network” also removes the requirement in the current definition of “medical laboratory network” that laboratories covered by such a network operate under a single approved pathology authority, as this is not always the case for such networks.

Item 39 includes a definition of ‘NATA’ in the Dictionary, that is, the National Association of Testing Laboratories.

Part 4 – Application and transitional provisions

Therapeutic Goods (Medical Devices) Regulations 2002

Item 40 – Subregulation 11.1(1), paragraphs (a)-(c) of definition of “transitional device”

Item 40 makes a minor amendment to the definition of a transitional device in regulation 11.1 of the Principal Regulations, to make it clearer that only those Class 1, 2 or 3 in-house IVDs that are in existence before 1 July 2017 are covered by the transitional arrangements set out in Division 11.1 of Part 11 of the Principal Regulations.

Item 41 – Subregulation 11.1(1), paragraph (d) of definition of “transitional device”

Item 41 makes a minor amendment to the definition of a transitional device in regulation 11.1 of the Principal Regulations, to make it clearer that only those Class 4 in-house IVDs that are in existence before 1 July 2016 are covered by the transitional arrangements set out in Division 11.1 of Part 11 of the Principal Regulations.

Item 42 and 43 – Regulation 11.15 and subregulation 11.17(1)

Items 42 and 43 make minor amendments to regulation 11.15 and subregulation 11.17(1) to reflect the clarification provided by item 41.

Items 44 and 45 – Subregulation 11.17(8) and new regulation 11.18

Regulation 11.17 sets out when those Class 4 in-house IVDs that are covered by the transitional arrangements in Division 11.1 and for which a conformity assessment certificate is applied for before 1 July 2016, will be subject to the new regulatory framework for IVDs introduced by Schedule 1 to the Therapeutic Goods (Medical Devices) Amendment Regulations 2010 (No.1) (the 2010 Amendments).

As item 4 removes the requirement for Class 4 in-house IVDs to have a conformity assessment certificate unless the laboratory opts to apply the full quality assurance procedures in Part 1 of Schedule 3 to their devices, there is a need to amend the transitional arrangements to ensure that the new framework can start applying to those transitional Class 4 in-house IVDs (i.e. those that are in existence before 1 July 2016) for which the manufacturing laboratory does not, before 1 July 2016, apply for a certificate.

In addition to where a laboratory does not apply for a certificate, regulation 11.17 also does not currently ensure that the new framework would start to apply for transitioning Class 4 in-house IVDs where:

- the laboratory applies for a certificate, but later withdraws that application before it is issued or finally determined (i.e. finally rejected); or

- the laboratory is issued a certificate and applies for the inclusion of their device in the Register (either before 1 July 2017 or, in the case of a certificate issued on or after 1 June 2017, within 30 days of the certificate being issued) but later withdraws that application before the device is included, or the application for inclusion is finally determined.

Item 44 therefore substitutes a new subregulation 11.17(8) which makes it clear that for any transitional Class 4 in-house IVD not covered by any of subregulations 11.17(2)-(7), the application of the new framework will be as determined under the new regulation 11.18.

This means that for laboratories that don't apply for a conformity assessment certificate before 1 July 2016 or who do so but later withdraw, or that apply for a certificate before 1 July 2016, are issued with one and apply for inclusion in the Register, but later withdraw - the point at which they must start complying with the new framework will be as determined under new regulation 11.18.

Item 45 then substitutes a new regulation 11.18, which determines when the new framework would begin to apply for transitional Class 4 in-house IVDs covered by the circumstances outlined above.

In addition, the removal of current subregulation 11.17(8) by item 44 also gives a laboratory that applies for a certificate in relation to a transitional Class 4 in-house IVD before 1 July 2016, and whose application is finally determined (i.e. finally rejected) after the commencement of this Amendment Regulation but before 1 July 2017, more time before the new framework would begin to apply to them in respect of their device.

Currently, laboratories in such circumstances would be subject to the new framework on the day the certificate application is finally determined (and this will be the case for any laboratories to which current subregulation 11.17(8) has applied before the commencement of this Amendment Regulation).

However, following the changes made by items 44 and 45, if a laboratory's application for a certificate was finally determined after the commencement of the Amendment Regulation and before 1 July 2017, new regulation 11.18 would apply, giving the laboratory until 30 June 2017 to apply for inclusion in the Register – noting that by reason of the amendment made by item 4, they would be able to do so without the need to first have a certificate in place.

The laboratory would continue to be covered by the transitional arrangements until the new framework started to apply to the device as determined under new regulation 11.18.

Table 1 below summarises the effect of new regulation 11.18:

Table 1

New provision	Scenario	Framework applies
11.18(2)	<ul style="list-style-type: none"> • an effective application for inclusion in the Register is made before 1 July 2017 • the device is included in the Register 	The day the device is included in the Register
11.18(3)	<ul style="list-style-type: none"> • an effective application for inclusion in the Register is made before 1 July 2017 • the application is withdrawn or finally determined (i.e. finally rejected) 	The day the application for inclusion is withdrawn or finally determined
11.18(4)	<ul style="list-style-type: none"> • an effective application for inclusion in the Register is not made before 1 July 2017 	1 July 2017

Item 45 also includes a minor amendment to repeal subregulation 11.19 – this subregulation is no longer be needed in light of the clarification provided by item 40.

Item 46 – Regulation 11.20

Item 46 makes a minor amendment to reflect the clarification provided by item 40.

Item 47 – Regulation 11.21

Item 47 principally makes a minor amendment to substitute a new regulation 11.21 that makes it clearer that the new framework for IVDs will apply to Class 1, 2 and 3 in-house IVDs from 1 July 2017. For laboratories with transitional Class 1, 2 or 3 in-house IVDs, this means, for example, that the obligation to notify the Secretary of the devices they are manufacturing only arises on 1 July 2017 (noting that, under new paragraph 6A.2(3)(a), they will have 20 working days after that date to do so). Any Class 1, 2 or 3 in-house IVDs coming into existence after that time will be subject to the new framework.

Item 48 – Division 11.3 – Application provisions relating to this Amendment Regulation

Item 48 sets out application arrangements for the measures in Parts 1 and 2 of the Schedule to this Amendment Regulation.

New regulation 11.25 sets out the application arrangements for the measures in Part 1 of the Schedule - which relate to new conformity assessment procedures for Class 4 in-house IVDs, and the removal of the requirement for most Class 4 in-house IVDs to obtain a conformity assessment certificate - for transitional Class 4 in-house IVDs.

Under subregulation 11.25(2), the amendments made by Part 1 apply to a transitional Class 4 in-house IVD on the later of the commencement of this Amendment Regulation and the day the device comes into existence, for the purposes of any of the matters listed in current subregulation 11.16(c)-(f) of the Principal Regulations. These cover applications for, and the issuing of, conformity assessment certificates, applications for inclusion in the Register and inclusion in the Register.

Subregulation 11.25(2) therefore ensures that Part 1 will apply to a transitional Class 4 in-house IVD in relation to any of these purposes at the same time as the 2010 Amendments would apply to the device for that purpose under regulation 11.16 or, if the 2010 Amendments have already started to apply to the device for that purpose, on the commencement of this Amendment Regulation.

Regulation 11.16 is designed to ensure that transitional Class 4 in-house IVDs, which are covered by the temporary arrangements in regulation 11.4 (these provide requirements in relation to the essential principles and conformity assessment procedures for transitional devices, during the transitional period) until the point at which the 2010 Amendments apply to them in full under Subdivision E of Division 11.1, are nevertheless able to be assessed against the requirements of the new IVD framework in relation to any applications for conformity assessment certificates or inclusion in the Register made during the transition period.

Subregulation 11.25(2) means, for example, that the amendments in Part 1 will apply to a transitional Class 4 in-house IVD for the purposes described in the previous paragraph:

- on the commencement of this Amendment Regulation in relation to a device for which an application for a conformity assessment certificate has already been made but not yet approved or finally determined, for the purposes of that application – the effect will be that the laboratory would then have the option of continuing with their application or withdrawing it and proceeding to apply directly for inclusion of the device in the Register (before 1 July 2017) on the basis of the changes proposed by item 4 and the conformity assessment procedures in new Part 6B of Schedule 3;
- on the commencement of this Amendment Regulation in relation to a device for which a conformity assessment certificate has already been issued, and an application is made for inclusion in the Register on or after the commencement day (but before 1 July 2017), for the purposes of that application – the effect will be that the laboratory would then have the option of applying the conformity assessment procedures in new Part 6B of Schedule 3, or the existing full quality assurance procedures in Part 1 of Schedule 3 (and relying on the certificate already issued), as part of their application for inclusion in the Register;
- on the day the device comes into existence, in relation to a device which comes into existence after the commencement of this Amendment Regulation, for the purposes of an application for a conformity assessment certificate (if one is applied for before 1 July 2016) and/or inclusion in the Register (provided this is applied for before 1 July 2017); and
- on the commencement of this Amendment Regulation, in relation to a device that is already in existence for which no application for a conformity assessment certificate has been made - the effect will be that the laboratory would then have the option of still choosing to apply for a certificate, or alternatively not applying for a certificate but instead applying directly for inclusion of the device in the Register (before 1 July 2017) on the basis of the changes made by item 4 and the conformity assessment procedures in new Part 6B of Schedule 3.

Under subregulation 11.25(3), the amendments made by Part 1 apply for all purposes to a transitional Class 4 in-house IVD on the later of the commencement of this Amendment Regulation and the transition day for the device (i.e. the point at which the 2010 Amendments apply to them in full under Subdivision E of Division 11.1 of the Principal Regulations).

Subregulation 11.25(3) therefore ensures that Part 1 will apply to a transitional Class 4 in-house IVD for all purposes at the same time as the 2010 Amendments would apply to the device for all purposes under regulations 11.17 and 11.18 (as amended or replaced under Part 4 of this Amendment Regulation) or, if the 2010 Amendments have already started to apply to the device for all purposes, on the commencement of this Amendment Regulation.

This means, for example, that the amendments in Part 1 will apply in relation to a transitional Class 4 in-house IVD:

- on the commencement of this Amendment Regulation, for a device for which a conformity assessment certificate was already issued, and which was included in the Register, before the commencement of this Amendment Regulation;
- on the commencement of this Amendment Regulation, for a device for which a conformity assessment certificate was issued, but for which an application for inclusion in the Register was finally determined (i.e. finally rejected), before the commencement of this Amendment Regulation;
- on the day the device is included in the Register, or the day an application to include the device in the Register is finally determined, where either of these occurs after the commencement of this Amendment Regulation and where one of subregulation 11.17(2)-(7), 11.18(2)-(4) applies.

New regulation 11.26 ensures that the amendments in Part 2 of the Schedule to this Amendment Regulation (which relate to changes to the conformity assessment procedures for Class 1, 2 and 3 in-house IVDs) will apply to transitional Class 1, 2 and 3 in-house IVDs (i.e. those in existence before 1 July 2017) at the same time as the 2010 Amendments apply to such products under the existing arrangements in Subdivision F of Division 11.1 of the Principal Regulations.

New regulation 11.26 also has the effect that if a laboratory that manufactures Class 1,2 or 3 in-house IVDs:

- has, before the commencement of this Amendment Regulation, notified the Secretary of their address and the details of the devices they are manufacturing, as required under current clause 1.2 of Part 6A of Schedule 3 to the Principal Regulations, they will be taken to have complied with the notification requirements in new subclause 6A.2 (in relation to the devices so notified); and
- notifies, between the commencement of this Amendment Regulation and 30 June 2017, the Secretary of the details of the devices they are manufacturing, in accordance with new subclauses 6A.2(2) and (3), they will also be taken to have complied with new subclause 6A.2 (in relation to the devices so notified).

In each case, the laboratory would not then need to notify the Secretary again of the information they had already provided, on or within 20 working days of 1 July 2017.

Statement of Compatibility with Human Rights

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

Therapeutic Goods (Medical Devices) Amendment (In Vitro Diagnostic Medical Devices) Regulation 2015

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 (Medical Devices) Amendment (In Vitro Diagnostic Medical Devices) Regulation 2015* (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 derived from the human body – generally, these are pathology tests and related instrumentation for testing human samples. IVDs can be commercially manufactured or developed and used “in-house” by a laboratory, including by adapting an existing commercial IVD.

On 1 July 2010 a new regulatory framework for IVDs was introduced through amendments to the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Principal Regulations), to regulate IVDs as medical devices under Chapter 4 of the Act (previously they were regulated as therapeutic devices under Part 3-2 of the Act). IVDs in existence then, and in-house IVDs coming into existence during the transition period, were given until 30 June 2014 to transition to the new framework. In 2015, this was extended until 30 June 2015 for commercial IVDs and until 30 June 2017 for in-house IVDs.

In recent times, concerns have arisen that manufacturers of in-house IVDs are experiencing, or are expected to experience, difficulties in complying with the new framework. In particular, the new framework requires Class 4 in-house IVDs to comply with the same conformity assessment procedures as commercial Class 4 IVDs, and requires Class 4 in-house IVDs to obtain a conformity assessment certificate before applying to include their devices in the Australian Register of Therapeutic Goods (this is also the case for Class 4 commercial IVDs). Industry has also expressed a desire for greater flexibility in relation to the conformity assessment requirements for Class 1-3 in-house IVDs.

The Amendment Regulation would amend the Principal Regulations to address these concerns, including by introducing alternative conformity assessment procedures for Class 4 in-house IVDs. This would allow laboratories to rely on accreditation by the National Association of Testing Authorities as complying with *ISO 15189 Medical laboratories-Requirements for quality and competence* - something most laboratories would already have for other reasons, e.g. so that certain pathology tests are eligible for Medicare rebates. The Amendment Regulation would also remove the need for laboratories relying on these new procedures to obtain a conformity assessment certificate, and give laboratories manufacturing Class 1-3 in-house IVDs a choice of ISOs to meet.

Human rights implications

The Amendment Regulation 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