

EXPLANATORY STATEMENT

Select Legislative Instrument No. 159, 2014

Therapeutic Goods Act 1989

Therapeutic Goods (Medical Devices) Amendment (Australian Manufacturers) 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.

Under section 41EA of the Act and subregulation 4.1(1) of the Therapeutic Goods (Medical Devices) Regulations 2002 (the Principal Regulations), a valid application for marketing approval cannot be made for a medical device that is manufactured in Australia unless the manufacturer of the device has applied to the Therapeutic Goods Administration (the TGA) for, and been issued, a conformity assessment certificate.

This contrasts with devices manufactured overseas, for which a TGA conformity assessment certificate is only needed before an application for marketing approval can be made if the device is of a type described in paragraphs 4.1(2)(a)-(e) of the Principal Regulations. These are higher risk products, such as devices (other than in vitro diagnostic medical devices) containing tissues, cells or substances of microbial or recombinant origin, and Class 4 in vitro diagnostic medical devices.

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.

Sponsors of all medical devices, wherever manufactured, must certify that their devices comply with these requirements when they apply for marketing approval, and must also certify that either they have information to substantiate that compliance or are able to obtain it from the manufacturer.

Overseas manufacturers (other than those manufacturing higher risk devices mentioned in paragraphs 4.1(2)(a)-(e) of the Principal Regulations, for which a conformity assessment certificate is mandatory) have the option of applying to the TGA for a conformity assessment certificate. They also have the option of using the services of a private conformity assessment body to assess their manufacturing processes and validate that they comply with relevant regulatory requirements.

These bodies are approved and supervised by regulators in other countries, including in particular in Europe, and an assessment by such a body of a manufacturer's processes and the devices being manufactured is expected to deliver the same outcome as an assessment by the TGA in terms of examining and verifying the manufacturer's compliance with manufacturing standards, and safety and performance requirements for the devices in question.

The Therapeutic Goods (Medical Devices) Amendment (Australian Manufacturers) Regulation 2014 (the Regulation) amends the Principal Regulations to place Australian manufacturers on the same footing as overseas manufacturers in this regard in relation to conformity assessment certificates for medical devices other than those higher risk devices noted above.

This allows Australian manufacturers also to use private conformity assessment bodies for all medical devices other than a higher risk device of a kind referred to in paragraphs 4.1(2)(a)-(e) of the Principal Regulations.

This measure provides Australian medical device manufacturers with greater flexibility in relation to demonstrating compliance with conformity assessment requirements, as well as providing for flow-on benefits such as a reduction in administrative costs associated with the issuing of conformity assessment certificates.

The Regulation also includes a small number of minor, consequential amendments.

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

The Act does not specify conditions that would 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 5 November 2014.

Consultation

The TGA released a public consultation paper in January 2013 on a proposal to allow third party conformity assessment for Australian medical device manufacturers, inviting submissions. A request for further public input was also invited in May 2013. Responses to both rounds of consultation were received from a range of industry stakeholders, healthcare professionals and consumer representative organisations.

In both instances, industry stakeholders were supportive of the proposal, and consumer and professional representatives and medical device procurers, expressed some concern about the reduction in direct TGA oversight of manufacturers.

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

Details of the proposed *Therapeutic Goods (Medical Devices) Amendment (Australian Manufacturers) Regulation 2014*

Section 1 – Name of Regulation

This section provides for the regulation to be referred to as the *Therapeutic Goods (Medical Devices) Amendment (Australian Manufacturers) Regulation 2014*.

Section 2 – Commencement

This section provides for the regulation to commence on 5 November 2014.

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

Schedule 1 – Amendments of the *Therapeutic Goods (Medical Devices) Regulations 2002*

Therapeutic Goods (Medical Devices) Regulations 2002

Items 1 and 2 – Regulation 3.5 (heading) and subregulation 3.5(1)

These items make a minor, consequential change to subregulation 3.5(1), and introduce a new heading for regulation 3.5, of the Principal Regulations.

Subregulation 3.5(1) allows a power or function of the Secretary in relation to assessing whether an overseas manufacturer has correctly applied relevant manufacturing standards (known as ‘conformity assessment procedures’) in their production processes to be exercised by a body or authority (including a private conformity assessment body) that the Secretary is satisfied has appropriate expertise to do so.

These powers and functions include, for example, assessing whether a device manufacturer has implemented a quality management system for the design, production, packaging, labelling and final inspection of its devices.

Item 2 removes the reference in subregulation 3.5(1) to overseas manufacture, with the effect that Australian manufacturers can also use the services private conformity assessment bodies to conduct such assessments.

Item 1 introduces a new heading for regulation 3.5(1) to reflect the removal of the reference to medical devices manufactured outside Australia.

Item 3 – Subregulation 4.1

This item repeals subregulation 4.1(1) of the Principal Regulations, thus removing the current requirement in that provision for all Australian medical device manufacturers to have applied

for, and been issued, a conformity assessment certificate before marketing approval can be sought for their devices.

The effect of this item, taken together with the amendment made by item 6, is to place Australian medical device manufacturers on the same footing as overseas manufacturers – i.e. device manufacturers, whether based in Australia or overseas, will only need a conformity assessment certificate issued by the TGA if they are engaged in the manufacture of certain kinds of medical devices (listed in paragraphs 4.1(2)(a)-(e)).

Item 4 – Subregulation 4.1(2)

This item makes a minor formatting change to subregulation 4.1(2) as a consequence of the amendments made by items 3 and 7.

Item 5 – Subregulation 4.1(2)

This item makes a minor formatting change to subregulation 4.1(2) as a consequence of the amendment made by item 7.

Item 6 – Subregulation 4.1(2)

Currently under subregulation 4.1(2) of the Principal Regulations, a conformity assessment certificate must have been issued by the TGA before marketing approval can be sought for certain kinds of medical devices that are manufactured overseas – e.g. medical devices (other than in vitro diagnostic medical devices) containing non-viable tissues of animal origin.

Item 6 removes the reference to overseas manufacture from subregulation 4.1(2), with the effect that subregulation 4.1(2) applies to require any medical device manufacturer engaged in the production of one of these kinds of devices to obtain a conformity assessment certificate, whether they are based overseas or in Australia.

Item 7 – Subregulation 4.1(3)

Item 7 repeals subregulation 4.1(3), principally as a consequence of the repeal of subregulation 4.1(1).

Subregulation 4.1(3) exempts specified kinds of medical devices from the requirement in subregulations 4.1(1) and (2) to obtain a conformity assessment certificate. With the repeal of subregulation 4.1(1), subregulation 4.1(3) is no longer necessary.

In addition, some of the kinds of devices in subregulation 4.1(3) do not require a conformity assessment certificate in any event, as they are devices which, under the Act, are not required to be included in the Australian Register of Therapeutic Goods (the Register) – e.g. devices approved under section 41HB of the Act for use solely in clinical trials.

Item 8 – Subparagraph 5.3(1)(j)(viii)

Item 8 replaces current subparagraph 5.3(1)(j)(viii) of the Principal Regulations with a new subparagraph of that number, incorporating a minor, consequential change to reflect the amendments introduced by item 2 above.

Subparagraph 5.3(1)(j)(viii) currently requires the Secretary to audit an application for the inclusion in the Register of an in vitro diagnostic medical device manufactured overseas in specified circumstances. Those circumstances are where the device is one in relation to which the Secretary is not satisfied, under subregulation 3.5 of the Principal Regulations, that a

private conformity assessment body has the expertise and authority to assess the suitability of the manufacturing processes of the overseas manufacturer of the device.

As item 2 amends subregulation 3.5 to remove any distinction between medical devices manufactured in Australia or overseas in relation to the Secretary's ability to authorise a private body to assess manufacturing processes, there is a need to also amend subparagraph 5.3(1)(j)(viii) to the same end.

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 (Australian Manufacturers) 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 (Medical Devices) Amendment (Australian Manufacturers) Regulation 2014* (the Amendment Regulation) is made under subsection 63(1) of the *Therapeutic Goods Act 1989* (the Act). Under section 41EA of the *Therapeutic Goods Act 1989* and subregulation 4.1(1) of the Therapeutic Goods (Medical Devices) Regulations 2002 (the Principal Regulations), an application for marketing approval cannot be made for a medical device manufactured in Australia unless the manufacturer has applied to the Therapeutic Goods Administration (TGA) for, and been issued, a conformity assessment certificate. This contrasts with devices manufactured overseas, for which a TGA conformity assessment certificate is only required before an application can be made for marketing approval if the device involved is of a higher risk type described in paragraphs 4.1(2)(a)-(e) of the Principal Regulations.

Conformity assessment certificates signify a range of matters about the manufacture of the 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. Sponsors of devices must certify that their devices comply with these requirements when applying for marketing approval, and conformity assessment certificates substantiate that compliance for manufacturers required to obtain them. Overseas manufacturers, however, are able to use the services of private conformity assessment bodies to verify such matters.

The purpose of the Amendment Regulation is to amend the Principal Regulations to place Australian manufacturers on the same footing as overseas manufacturers in regard to the need for conformity assessment certificates for medical devices other than those higher risk devices mentioned above, providing Australian manufacturers with greater flexibility in relation to demonstrating compliance with conformity assessment compliance and benefits such as a reduction in associated administrative costs.

Human rights implications

As the Amendment Regulation does not introduce any changes to the Principal Regulations other than to implement the measure outlined 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