

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Authorised Supply of Specified Medical Devices) Rules March 2018

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.

The *Therapeutic Goods Amendment (2016 Measures No.1) Act 2017* (the Amendment Act) recently amended the Act to, in particular, support the implementation of several key recommendations of the Expert Panel Review of Medicines and Medical Device Regulation (the Review) agreed to by the Australian Government in its response to the Review. The Expert Panel was established to identify areas of the regulation of medicines and medical devices which could be streamlined while maintaining the safety and quality of therapeutic goods in Australia, and made 58 recommendations. The Australian Government supported 56 of the 58 recommendations for reform. The Amendment Act addressed a first tranche of these recommendations.

One of the reforms supported by the Amendment Act was to enable health practitioners to supply certain unapproved therapeutic goods (i.e. goods that are not included in the Australian Register of Therapeutic Goods (the Register)) – principally those with an established history of use in similar overseas countries, or in Australia through the existing provisions allowing access to unapproved therapeutic goods – to their patients by way of notification to the TGA, rather than (as would otherwise be the case) requiring pre-approval. For medical devices, this involved the insertion of new subsections 41HC(6) to (6G) in the Act

Subsection 41HC(6) of the Act provides that the Minister may, by legislative instrument, make rules authorising any health practitioner who is included in a specified class of health practitioners to supply a specified kind of medical device for use in the treatment of humans to the class or classes of recipients specified in those rules, so long as:

- (a) the kind of medical device is supplied in the circumstances specified in those rules; and
- (b) the conditions (if any) specified in those rules are satisfied.

The Rules therefore specify classes of health practitioners, kinds of medical devices, classes of recipients, circumstances and conditions and set out the relevant authorisations, for the purposes of subsection 41HC(6). One such condition is that the health practitioner must ensure that the device is supplied in accordance with good medical practice – more detail on the meaning of this term is set out in the explanation of the effect of section 4 of the Rules in the Attachment.

Subsection 41HC(6A) of the Act provides that, in making rules under subsection (6), the Minister must comply with:

- (a) such requirements (if any) as are prescribed by the regulations; and
- (b) such restrictions (if any) as are prescribed by the regulations; and

(c) such limitations (if any) as are prescribed by the regulations.

No regulations have been made for the purposes of subsection 41HC(6A).

Subsection 41HC(6B) of the Act imposes a requirement for a health practitioner to notify a supply of a medical device under rules made under subsection 41HC(6) to the Secretary after the health practitioner has supplied the medical device. The health practitioner must do so in accordance with subsection 41HC(6C) of the Act (principally, this relates to ensuring that the notification contains the information prescribed in the regulations for the purposes of subsection 41HC(6C) – e.g. the practitioner’s name, and medical condition for which the medical device was supplied to the patient).

The Rules are made for the purposes of subsection 41HC(6).

Details of the Rules are set out in the Attachment.

The Rules are a legislative instrument for the purposes of the *Legislation Act 2003*.

This instrument replaces the Therapeutic Goods (Authorised Supply of Medical Devices) Rules September 2017 (the September 2017 Rules) and incorporates the following changes compared to the September 2017 Rules:

- (a) the clarification of the purpose(s) (statements of therapeutic use) for each medical device; and
- (b) the addition of a further 14 medical devices that have an established history of safe use.

Consultation

Extensive stakeholder consultation was undertaken with consumers, industry and health professionals as part of the Review. A public consultation on the proposed changes to introduce a new, streamlined pathway to access unapproved therapeutic goods considered to have an established history of safe use was also completed, in the lead up to the making of the first edition of these Rules, which were registered on 3 July 2017. During that consultation, stakeholders were advised of the process for adding and removing items from the Rules, including in particular that from time to time products may be added to, or removed from, the instrument, and that this may not always be preceded by consultation. As such, the main changes that are incorporated in this instrument as compared to the September 2017 Rules have not been specifically consulted on. As these changes principally add a number of new products that can be supplied by medical practitioners to their patients by notification, without the need for pre-approval, this will result in greater flexibility and ease of access for both patients and health practitioners.

Other changes concerned are minor and machinery in nature and principally relate to clarifications and the removal of unintended errors.

Authority: Subsection 41HC(6) of the
Therapeutic Goods Act 1989

Details of the *Therapeutic Goods (Authorised Supply of Specified Medical Devices) Rules March 2018***Section 1 – Name**

This section provides for the Rules to be referred to as the *Therapeutic Goods (Authorised Supply of Specified Medical Devices) Rules March 2018*.

Section 2 – Commencement

This section provides for the Rules to commence the day after they are registered.

Section 3 – Authority

This section provides that the Rules are made under subsection 41HC(6) of the *Therapeutic Goods Act 1989*.

Section 4 – Authorisation to supply medical devices

This section sets out the relevant authorisations.

The kinds of medical devices that may be supplied under the Rules are specified in table 1.

Subsection 4(1) provides that a health practitioner of the kind specified in an item in table 1 is authorised to supply the medical device covered by that table item to a patient of the health practitioner.

Subsection 4(2) provides that another health practitioner is authorised to supply the medical device to a patient of the first health practitioner if requested to do so by the first health practitioner.

In both cases, the supply must be for a purpose specified in the relevant table item.

The supply of a medical device under the Rules is subject to conditions. In the case of supply by a health practitioner to their own patient, the health practitioner must inform the patient (or a parent or guardian of the patient) that the medical device is not included in the Australian Register of Therapeutic Goods (the Register), must receive informed consent, and must supply the medical device in accordance with good medical practice.

The TGA document titled *Special Access Scheme Guidance for health practitioners and sponsors* published on the TGA website, which includes guidance on the supply of unapproved goods under these Rules, explains that ‘good medical practice’ refers to a series of standards that health practitioners should adhere to when treating patients. These standards are generally patient-centred and comprise ethical and professional benchmarks expected by a health practitioner’s professional peers, as well as the community. For example, registered medical practitioners operate in accordance with the principles in the Medical Board of Australia’s ‘*Good Medical Practice: A Code of Conduct for Doctors in Australia*’, and dental practitioners would be expected to comply, in most cases, with the Dental Board of Australia’s ‘*Code of Conduct for registered health practitioners*’.

Given the above, it is expected that health practitioners in particular, and patients, would be familiar with, and understand, the meaning of this term.

The health practitioner supplying the medical device (whether under subsection 4(1) or (2)) must notify the TGA, and the sponsor of the medical device, if the health practitioner becomes aware of any adverse event suffered by the patient or any defect in the medical device.

Statement of Compatibility with Human Rights

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

Therapeutic Goods (Authorised Supply of Specified Medical Devices) Rules March 2018

The Rules are 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 Rules are made under subsection 41HC(6) of the *Therapeutic Goods Act 1989* (the Act). They commence the day after they are registered.

The *Therapeutic Goods Amendment (2016 Measures No.1) Act 2017* (the Amendment Act) amended the Act to, in particular, support the implementation of several key recommendations of the Expert Panel Review of Medicines and Medical Device Regulation (the Review) agreed to by the Australian Government in its response to the Review (see www.tga.gov.au). The Expert Panel was established to identify areas of the regulation of medicines and medical devices which could be streamlined while maintaining the safety and quality of therapeutic goods in Australia, and made 58 recommendations. The Australian Government supported 56 of the 58 recommendations for reform, and the Amendment Act addressed a first tranche of these recommendations.

One of the reforms supported by the Amendment Act was to enable health practitioners to supply certain unapproved therapeutic goods (i.e. goods that are not included in the Australian Register of Therapeutic Goods (the Register)) – principally those with an established history of use in similar overseas countries – to their patients by way of notification to the TGA, rather than by requiring pre-approval. For medical devices, this involved the insertion of new subsections 41HC(6) to (6G) in the Act.

The Rules are made for the purposes of subsection 41HC(6) and authorise health practitioners included in a specified class of health practitioners to supply specified kinds of medical devices to specified classes of recipients.

This instrument replaces the Therapeutic Goods (Authorised Supply of Medical Devices) Rules September 2017 (the September 2017 Rules) and incorporates the following changes compared to the September 2017 Rules:

- (a) the clarification of the purpose(s) (statements of therapeutic use) for each medical device; and
- (b) the addition of a further 14 medical devices that have an established history of safe use.

Human rights implications

The Rules do 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.

Larry Kelly, delegate of the Minister for Health