

## **EXPLANATORY STATEMENT**

### *Therapeutic Goods Act 1989*

#### *Therapeutic Goods (Authorised Supply of Specified Biologicals) Rules April 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) 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, 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, 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 biologicals, this involved the insertion of new subsections 32CM(7A) to (7H) in the Act.

Subsection 32CM(7A) 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 biological for use in the treatment of humans to the class or classes of recipients specified in those rules, so long as:

- (a) the biological 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, biologicals, classes of recipients, circumstances and conditions and set out the relevant authorisations, for the purposes of subsection 32CM(7A). One such condition is that the health practitioner must ensure that the biological 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 32CM(7B) of the Act provides that, in making rules under subsection (7A), 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 32CM(7B).

Subsection 32CM(7C) of the Act imposes a requirement for a health practitioner to notify a supply of a biological under rules made under subsection 32CM(7A) to the Secretary after the health practitioner has supplied the biological. The health practitioner must do so in accordance with subsection 32CM(7D) of the Act (principally, this relates to ensuring that the notification contains the information prescribed in the regulations for the purposes of subsection 32CM(7D) – e.g. the practitioner’s name, and the medical condition for which the biological was supplied to the patient).

The Rules are made for the purposes of subsection 32CM(7A).

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 Specified Biologicals) March 2018*, registered on 14 March 2018, to incorporate the following changes:

- (a) the inclusion of a number of indications for each entry that were inadvertently omitted from the Rules registered on 14 March 2018.

These new Rules do not introduce any additional entries to the instrument.

## **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 14 March 2018 Rules have not been specifically consulted on. As these changes principally relate to the refinement of the intended circumstances in which these products can be supplied by medical and dental practitioners to their patients by notification, this will ensure safe use for patients.

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

Authority: Subsection 32CM(7A) of the  
*Therapeutic Goods Act 1989*

**Details of the *Therapeutic Goods (Authorised Supply of Specified Biologicals) Rules April 2018***

**Section 1 – Name**

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

**Section 2 – Commencement**

This section provides for the Rules to commence on 1 April 2018.

**Section 3 – Authority**

This section provides that the Rules are made under subsection 32CM(7A) of the *Therapeutic Goods Act 1989*.

**Section 4 – Authorisation to supply biologicals**

This section sets out the relevant authorisations.

The biologicals 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 biological 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 biological 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 an indication specified in the relevant table item and the biological must be for administration through the route of administration mentioned in the relevant table item.

The supply of a biological 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 biological is not included in the Australian Register of Therapeutic Goods (the Register), must receive informed consent, and must supply the biological 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 biological (whether under subsection 4(1) or (2)) must notify the TGA, and the sponsor of the biological, if the health practitioner becomes aware of any adverse event suffered by the patient or any defect in the biological.

## 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 Biologicals) Rules April 2018

These 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 32CM(7A) of the *Therapeutic Goods Act 1989* (the Act). They commence on 1 April 2018.

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](http://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 biologicals, this involved the insertion of new subsections 32CM(7A) to (7H) in the Act

The Rules are made for the purposes of subsection 32CM(7A) and authorise health practitioners included in a specified class of health practitioners to supply specified biologicals to specified classes of recipients.

This instrument replaces the Therapeutic Goods (Authorised Supply of Specified Biologicals) Rules registered on 14 March 2018 and incorporates the following changes:

- (a) the inclusion of a number of indications for each entry that were inadvertently omitted from the Rules registered on 14 March 2018.

#### 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**