

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Biologicals—Conditions of Inclusion in Register) Determination 2018

The *Therapeutic Goods Act 1989* (the Act) provides for the establishment and maintenance of a national system of controls for the quality, safety, efficacy and timely availability of therapeutic goods that are used in, 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 (2017 Measures No.1) Act 2018* (the Amendment Act) amended the Act to 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. The Expert Panel was established to, principally, identify areas of medicines and medical devices regulation which could be streamlined while maintaining the safety and quality of therapeutic goods in Australia and made 58 recommendations, of which the Australian Government supported 56. The Amendment Act addressed a second tranche of these recommendations (following on from the *Therapeutic Goods Amendment (2016 Measures No.1) Act 2017*), including making amendments to the provisions in the Act relating to the conditions of inclusion of a biological in the Australian Register of Therapeutic Goods (the Register) to provide for a stronger post-market monitoring system for biologicals, (similar to that in place before the commencement of the Amendment Act for medicines).

Section 32EA of the Act provides that it is condition of inclusion of a biological in the Register that the person in relation to whom the biological is included must allow an authorised person to enter premises at which the person or any other person deals with the biological and to exercise certain powers of inspection. The Amendment Act amended section 32EA of the Act to extend this provision to premises at which the person in relation to whom the biological is included, or any other person, complies with record-keeping conditions under paragraph 32EC(2)(c) or keeps documents that relate to the biological.

The Amendment Act also amended section 32EC of the Act to enable the Minister, by legislative instrument, to determine conditions relating to reporting requirements. Prior to the commencement of the Amendment Act, section 32EC of the Act provided for the Minister, by legislative instrument, to determine conditions relating to various other matters, including the keeping of records relating to the biological and such other matters relating to the biological as the Minister thinks appropriate. Those matters remain within the scope of the instrument-making power.

The *Therapeutic Goods (Biologicals—Conditions of Inclusion in Register) Determination 2018* (the Determination) is made under section 32EC of the Act, and sets out standard conditions applying to the inclusion of biologicals in the Register. The conditions relate to reporting, record-keeping and the implementation of variations

Consultation

Extensive consultation was undertaken in 2014-15 with consumers, industry and health professionals as part of the Review. This consultation informed the development of the Amendment Act and associated instruments.

In late 2016, consultation was undertaken on the biovigilance responsibilities of sponsors of biologicals. Comments were sought from a range of interested parties. A total of ten submissions were received from the consultation. Of the submissions, there were four from manufacturers/sponsors, one from an industry group, three from organ and tissue banks, and two from other stakeholders. Six respondents were satisfied with the draft biovigilance guidelines and did not have further comments. The submissions informed the development of requirements imposed by the Determination through the incorporated document titled *Biovigilance Responsibilities of Sponsors of Biologicals – Australian requirements and recommendations*, with some changes to terminology and reporting requirements being made as a result of the submissions.

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

The Determination is compatible with human rights and freedoms recognised or declared under section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. A full statement of compatibility is set out in [Attachment B](#).

The Determination is a disallowable legislative instrument and commenced on the day after it was registered.

Details of the *Therapeutic Goods (Biologicals—Conditions of Inclusion in Register) Determination 2018*

Section 1 – Name

This section provides that the name of the Determination is the *Therapeutic Goods (Biologicals—Conditions of Inclusion in Register) Determination 2018*.

Section 2 – Commencement

This section provides that the Determination commences on the day after it is registered.

Section 3 – Definitions

This section provides definitions for certain terms used in the Determination that are not otherwise defined in the Act.

Section 4 – Conditions of inclusion in Register—reporting and record-keeping

This section specifies conditions relating to reporting and record-keeping requirements that apply to the inclusion of a biological in the Register. The person in relation to whom the biological is included in the Register must keep records of each distribution of the biological for at least 10 years after the distribution, and must comply with any requirements relating to record-keeping or reporting set out in the document titled *Biovigilance Responsibilities of Sponsors of Biologicals – Australian requirements and recommendations* (the biovigilance document), published by the Therapeutic Goods Administration in December 2017. This includes, for example, requiring sponsors to report serious adverse events and serious threats to public health relating to their products, and to nominate a contact person within their organisation to the TGA for biovigilance matters

The ten-year record-keeping requirement is consistent with conditions that have been imposed on the inclusion of biologicals on the Register under section 32ED of the Act at the time those biologicals have been so included.

The requirements in the biovigilance document are similar to those applying to medicines under regulation 15A of the *Therapeutic Goods Regulations 1990* and the document titled *Pharmacovigilance Responsibilities of Medicine Sponsors*.

The version of the biovigilance document incorporated by reference into the Determination is the version in place when the Determination commences. Copies of the biovigilance document can be downloaded, free of charge, from the TGA website (www.tga.gov.au).

Section 5 – Conditions of inclusion in Register—variations

This section specifies that it is a condition of inclusion of a biological in the Register that the person in relation to whom the biological is included in the Register not implement a variation to, or in relation to, the biological before the Secretary approves the variation by varying the entry in the Register that relates to the biological under section 9D of the Act.

This condition will ensure that the biological supplied by the sponsor will be the same as the biological approved under the Act, either at the time it is included in the Register or subsequently when it is varied.

This condition is consistent with conditions that have been imposed on the inclusion of biologicals on the Register under section 32ED of the Act at the time those biologicals have been so included.

Statement of compatibility with human rights

This statement is prepared in accordance with subsection 9(1) of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Therapeutic Goods (Biologicals—Conditions of Inclusion in Register) Determination 2018

The *Therapeutic Goods (Biologicals—Conditions of Inclusion in Register) Determination 2018* 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 legislative instrument

The *Therapeutic Goods (Biologicals—Conditions of Inclusion in Register) Determination 2018* (the Determination) is made under section 32EC of the Act, and sets out conditions applying to the inclusion of biologicals in the Australian Register of Therapeutic Goods (the Register). The conditions relate to reporting, record-keeping and the implementation of variations.

Human rights implications

As the Determination's only function is to set out conditions applying to the inclusion of biologicals in the Register, it does not engage any of the applicable rights or freedoms.

Conclusion

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

Dr Larry Kelly, delegate of the Minister for Health