

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Biologicals— Information that Must Accompany Application for Inclusion in Register) Determination July 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, agreed to by the Australian Government, and to provide greater clarity in relation to the processing of applications for the inclusion of therapeutic goods in the Australian Register of Therapeutic Goods (the Register) following the decision of the Federal Court in *Nicovations Australia Pty Ltd v Secretary of the Department of Health* [2016] FCA 394 (Nicovations).

The Court in *Nicovations* found that the process adopted by the Department (through the TGA) in not progressing the processing of applications that did not satisfy preliminary requirements was not consistent with the Court's construction of the operation of section 23 of the Act.

These preliminary requirements (which include, for example, requirements that an application has been made in accordance with the appropriate approved form for the type or subset of goods involved, and is accompanied by the type and amount of supporting information needed to evaluate the application), are designed to enable the effective management of resources by the Department in the review of products, and to create certainty for sponsors as to the status of their products. A full evaluation process represents a considerable investment in, and use of, resources. As resources are finite, if an inaccurate or deficient application must nevertheless be fully evaluated, this could cause delay in the processing of other applications.

As such, the Amendment Act introduced measures to make it clear that an application for the inclusion of a medicine, biological or medical device in the Register must meet certain preliminary requirements before the Secretary is required to commence evaluating the application, and that the Secretary has the power to refuse an application prior to evaluating it if the application does not meet the requirements for a proper application.

In particular in respect of biologicals, the Amendment Act introduced new section 32DDA to the Act. Section 32DDA sets out the preliminary assessment requirements relating to applications for the inclusion of Class 2, Class 3 or Class 4 biologicals in the Register. These requirements include a requirement that the application be accompanied by supporting information that is of a kind determined under subsection 32DDA(9), and that the information is in a form determined under subsection 32DDA(10).

Subsection 32DDA(9) of the Act relevantly provides that the Secretary may, by legislative instrument, determine a kind of information for the purposes of the application of subparagraph 32DDA(2)(d)(i) of the Act to a class of biologicals.

Subsection 32DDA(10) of the Act relevantly provides that the Secretary may, by legislative instrument, determine a form of information for the purposes of the application of subparagraph 32DDA(2)(d)(ii) to a class of biologicals.

The *Therapeutic Goods (Biologicals— Information that Must Accompany Application for Inclusion in Register) Determination July 2018* (the Determination) is made under subsections 32DDA(9) and (10), for the purpose of the application of subparagraphs 32DDA(2)(d)(i) and (ii) to applications to include Class 2, 3 or 4 biologicals in the Register. The Determination repeals and replaces the *Therapeutic Goods (Biologicals— Information that Must Accompany Application for Inclusion in Register) Determination 2018*. This Determination includes an updated reference to the *Dossier requirements for Class 2, 3 and 4 biologicals, Australian Regulatory Guidelines for Biologicals* (which is accessible for free from the TGA website). It also includes an updated reference to the most recent version of the *General Dossier Requirements* document. The requirements for the purposes of this instrument remain the same.

Before the commencement of the Amendment Act, requirements relating to the kind and form of information to accompany an application for inclusion for a Class 2, Class 3 or Class 4 biological were imposed under section 32DD of the Act, which was the equivalent, for such biologicals, of section 23 of the Act for medicines as was in force before the commencement of the Amendment Act. While section 32DD was amended by the Amendment Act, the nature of the requirements imposed by the Determination is similar to those that were previously imposed under the then section 32DD.

The information required under the Determination to accompany an application is necessary in order to enable the Secretary to undertake a full evaluation of the application in accordance with section 32DE of the Act (which sets out the matters that the Secretary must have regard to when evaluating an application for inclusion in the Register for Class 2, Class 3 or Class 4 biological, e.g. whether the quality safety and efficacy of the biological for the purpose for which it is to be used has been satisfactorily established), and it is information that sponsors would be expected to have available when they apply for marketing approval. The form in which the information must be provided is also appropriate to ensuring that an evaluation can be undertaken efficiently.

The Determination itself is minor and machinery in nature, as the requirements imposed are similar to those in place before the commencement of the Amendment Act. Accordingly no specific consultation has been undertaken on the content of the Determination.

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— Information that Must Accompany Application for Inclusion in Register) Determination July 2018*

Section 1 – Name

This section provides that the name of the Determination is the *Therapeutic Goods (Biologicals— Information that Must Accompany Application for Inclusion in Register) Determination July 2018*.

Section 2 – Commencement

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

Section 3 – Schedules

This section provides that an instrument specified in a Schedule to this instrument is amended or repealed a set out in the applicable items in the Schedule concerned, and any other item in a Schedule has effect according to its terms.

Section 4 – Definitions

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

Section 5 – Applications to which this instrument applies

This section provides that the Determination applies to applications to include Class 2, 3 and 4 biologicals in the Register.

Section 6 – Kind of information

This section specifies the kind of information that must be provided with an application to which the instrument applies. The information is the information specified in the document *Dossier Requirements for Class 2, 3 and 4 Biologicals, Australian Regulatory Guidelines for Biologicals* (ARGB), under the heading ‘Technical Requirements’, published by the TGA before the commencement of the Determination. Copies of this document are available on the TGA’s website, free of charge, and the Determination includes information in relation to the intended manner of incorporation of this document.

Section 7 – Form of information

This section specifies the form in which any required information must be provided. The information must be provided in a dossier consistent with the TGA document titled *General dossier requirements*, version 1.4, published in July 2018, a copy of which is available on the TGA’s website, free of charge.

Schedule 1 – Repeals

Therapeutic Goods (Biologicals— Information that Must Accompany Application for Inclusion in Register) Determination 2018

Item 1

Item 1 provides for the repeal of the *Therapeutic Goods (Biologicals— Information that Must Accompany Application for Inclusion in Register) Determination 2018*. This Determination effectively replaces the *Therapeutic Goods (Biologicals— Information that Must Accompany Application for Inclusion in Register) Determination 2018*.

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— Information that Must Accompany Application for Inclusion in Register) Determination July 2018

The *Therapeutic Goods (Biologicals— Information that Must Accompany Application for Inclusion in Register) Determination July 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

This instrument is made under subsections 32DDA(9) and (10) of the *Therapeutic Goods Act 1989* (the Act) by a delegate of the Minister for Health. The purpose of the Determination is to set out the kind of information that must accompany an application for the inclusion of a biological in the Register, and the form in which that information must be provided.

The *Therapeutic Goods Amendment (2017 Measures No. 1) Act 2018* amended the Act to provide for the preliminary assessment of applications for registration of therapeutic goods. Under paragraph 32DDA(2)(d) of the Act as amended an application must be accompanied by information that is of a kind determined under subsection 32DDA(9) of the Act and in a form determined under subsection 32DDA(10) of the Act. The only persons on whom requirements are imposed are applicants for the inclusion of biologicals in the Register. The requirements are reasonably adapted to the need to ensure that the quality, safety and efficacy of the biologicals have been satisfactorily established.

Human rights implications

As this instrument does not introduce any requirements other than those outlined above, it would not appear to 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 Jane Cook,
Delegate of the Secretary of the Department of Health