

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (OTC Medicines—Information that Must Accompany Application for Registration) Determination August 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) recently amended the Act to, among other things (including in particular 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), 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 has provided the necessary 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 evaluate 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, the Amendment Act introduced new sections 23A and 23B to the Act. Section 23A provides for the Secretary, by notifiable instrument, to specify different classes of therapeutic goods for the purposes of section 23B. Section 23B sets out the preliminary assessment requirements relating to applications for the registration of therapeutic goods (principally prescription medicines, over the counter medicines and registrable complementary medicines), and the listing of medicines under section 26AE of the Act (listable medicines which are to be evaluated by the Secretary in relation to their efficacy). These requirements include a requirement that the application be accompanied

by supporting information that is of a kind determined under subsection 23B(9), and that the information is in a form determined under subsection 23B(10).

Subsection 23B(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 23B(2)(d)(i) of the Act to a class of therapeutic goods that is specified under section 23A of the Act.

Subsection 23B(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 23B(2)(d)(ii) to a class of therapeutic goods that is specified under section 23A.

Under section 23A, most over the counter medicines are specified as a class of therapeutic goods (other than the small number of over the counter medicines for which applications are evaluated by the Prescription Medicines Authorisation Branch in the Therapeutic Goods Administration). The *Therapeutic Goods (OTC Medicines—Information that Must Accompany Application for Registration) Determination August 2018* (the Determination) is made under subsections 23B(9) and (10) for the purpose of the application of subparagraphs 23B(2)(d)(i) and (ii) to applications to register goods of that class.

Before the commencement of the Amendment Act, requirements relating to the kind and form of information that was required to accompany an application for registration were imposed under section 23 of the Act. While that section was repealed and replaced by the Amendment Act, the nature of the requirements imposed by the Determination is similar to those that were previously imposed under the former section 23. The information required to accompany an application is necessary to enable the Secretary to undertake a full evaluation of the application in accordance with section 25 of the Act, and is information that sponsors would be expected to have available when they apply for registration. The form in which the information must be provided is appropriate to ensuring that the evaluation can be undertaken efficiently.

The Determination replaces the *Therapeutic Goods (OTC Medicines—Information that Must Accompany Application for Registration) Determination 2018*, registered on 27 April 2018, to reflect the update to the *General Dossier Requirements* guidance document (referred to in the *Therapeutic Goods (OTC Medicines—Information that Must Accompany Application for Registration) Determination 2018* by reference to the version 1.3, March 2018 version of that document), to the 1.4 version of that document that was published on the TGA's website (tga.gov.au) recently in July 2018. All documents referred to in the Determination are available from the TGA's website for free.

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.

Attachment A

Details of the *Therapeutic Goods (OTC Medicines—Information that Must Accompany Application for Registration) Determination August 2018*

Section 1 – Name

This section provides that the name of the Determination is the *Therapeutic Goods (OTC Medicines—Information that Must Accompany Application for Registration) Determination August 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 – Applications to which this instrument applies

This section provides that the Determination applies to applications to register over the counter medicines. This does not include the small number of over the counter medicines for which applications are evaluated by the Prescription Medicines Authorisation Branch in the TGA. Applications in relation to those medicines are covered by the *Therapeutic Goods (Prescription Medicines—Information that Must Accompany Application for Registration) Determination 2018*.

Section 5 – 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 various specified documents published by the TGA before the commencement of the Determination. Copies of those documents are available on the TGA's website, free of charge, and the Determination includes information in relation to the intended manner of incorporation of each of these documents.

Section 6 – 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.

Attachment B

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 (OTC Medicines—Information that Must Accompany Application for Registration) Determination August 2018

The *Therapeutic Goods (OTC Medicines—Information that Must Accompany Application for Registration) Determination August 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 23B(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 registration of an over the counter medicine, 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 23B(2)(d) of the Act as amended an application must be accompanied by information that is of a kind determined under subsection 23B(9) of the Act and in a form determined under subsection 23B(10) of the Act. The only persons on whom requirements are imposed are applicants for the registration of therapeutic goods (principally, these are prescription medicines, over the counter medicines and registrable complementary medicines). The requirements are reasonably adapted to the need to ensure that the quality, safety and efficacy of the goods have been satisfactorily established.

The Determination replaces the *Therapeutic Goods (OTC Medicines—Information that Must Accompany Application for Registration) Determination 2018*, registered on 27 April 2018, to reflect the update to the *General Dossier Requirements* guidance document (referred to in the *Therapeutic Goods (OTC Medicines—Information that Must Accompany Application for Registration) Determination 2018* by reference to the version 1.3, March 2018 version of that document), to the version 1.4 of that document that was published on the TGA's website (tga.gov.au) recently in July 2018.

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