

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Prescription Medicines—Kind of Information that Must Accompany Application for Registration) Determination 2022

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 Act is administered by the Therapeutic Goods Administration (“the TGA”) within the Australian Government Department of Health.

The *Therapeutic Goods Amendment (2017 Measures No. 1) Act 2018* (“the Amendment Act”) amended the Act to, among other things, 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. In particular, the Amendment Act introduced measures to require an application for the inclusion of a medicine, biological or medical device in the Register to meet certain preliminary requirements before the Secretary is required to evaluate the application. The Amendment Act also provided the Secretary with the power to refuse an application prior to evaluation if the application does not meet those requirements.

These requirements include that an application has been made in accordance with the appropriate approved form for the relevant class of therapeutic goods, and is accompanied by the necessary kind of information needed to evaluate the application. The requirements are designed to enable the effective management of resources by the Department in the evaluation of therapeutic goods, and to create certainty for sponsors as to the appropriate regulatory pathway for their products. A full evaluation process represents a considerable investment in, and use of, Commonwealth resources. Consequently, there are considerable efficiencies to be gained in mandating content and form requirements for applications to provide clarity regarding application requirements, streamline application and evaluation processes, and prevent delays in evaluating applications.

Specifically, 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, and the listing of medicines under section 26AE of the Act. These requirements include that the application must be accompanied by information that is of a kind determined under subsection 23B(9) (subparagraph 23B(2)(d)(i) of the Act refers), and that the information is in a form determined under subsection 23B(10) (subparagraph 23B(2)(d)(ii) of the Act refers).

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.

Classes of therapeutic goods are specified in the *Therapeutic Goods (Classes of Therapeutic Goods) Instrument 2018* (“the Classes Instrument”), which is made under section 23A of the Act. The Classes Instrument includes the class ‘prescription and other medicines’, to which the *Therapeutic Goods (Prescription Medicines—Kind of Information that Must Accompany Application for Registration) Determination 2022* (“the Determination”) applies. Section 4 of the Classes Instrument specifies the following kinds of medicines as ‘prescription and other medicines’:

- prescription and other medicines specified in items 1 to 13 of Part 1 of Schedule 10 to the *Therapeutic Goods Regulations 1990*;
- medicines containing oral nitrates for the treatment of heart disease;

- nasal corticosteroids;
- metered-dose asthma inhalers; and
- transdermal nicotine patches.

The Determination is made under subsection 23B(9) of the Act for the purposes of subparagraph 23B(2)(d)(i). It has the effect of determining that an application for the registration of a prescription medicine must be accompanied by the kind of information specified for the particular medicine in the following TGA documents:

- *CTD Module 1: Administrative information and prescribing information for Australia* (Version 4.3, December 2020); and
- *Mandatory requirements for an effective application* (Version 4.1, June 2022).

Incorporation by reference

The Determination incorporates by reference the *Therapeutic Goods (Classes of Therapeutic Goods) Instrument 2018*, which is a notifiable instrument made under section 23A of the Act. This instrument specifies different classes of therapeutic goods for the purposes of section 23B of the Act and is freely available on the Federal Register of Legislation at www.legislation.gov.au.

The following documents published by the TGA are also incorporated by reference in the Determination:

- the document titled *CTD Module 1: Administrative information and prescribing information for Australia* (Version 4.3, December 2020); and
- the document titled *Mandatory requirements for an effective application* (Version 4.1, June 2022).

These two documents describe the information that must be submitted to support an application for the registration of a prescription or other medicine under section 23 of the Act. They are both freely available from the TGA website at www.tga.gov.au.

The above three documents are incorporated as in force or existing at the commencement of the Determination, in accordance with paragraph 14(1)(b) of the *Legislation Act 2003*.

Consultation

No specific consultation was undertaken in relation to the making of the Determination, principally as its making reflects arrangements that have been in place on an administrative basis since the introduction of the amendments described above by the Amendment Act (and on that basis is principally minor and machinery in nature).

Also relevant to the decision not to specifically consult on the making of the Determination is that it complements and reflects the amendments made to the Act by the Amendment Act, in relation to the introduction of sections 23A and 23B to the Act for the purpose of providing greater clarity in relation to the preliminary assessment of applications for the registration and listing of therapeutic goods in the Register.

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.

As the Determination is consequential to the relevant amendments made by the Amendment Act, and its effect is minor and machinery in nature, a Regulation Impact Statement is not required (OPBR Ref 21178).

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 commences the day after the instrument is registered on the Federal Register of Legislation.

Details of the *Therapeutic Goods (Prescription Medicines—Kind of Information that Must Accompany Application for Registration) Determination 2022*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods (Prescription Medicines—Kind of Information that Must Accompany Application for Registration) Determination 2022* (“the Determination”).

Section 2 – Commencement

This section provides that the Determination commences on the day after registration on the Federal Register of Legislation.

Section 3 – Authority

This section provides that the legislative authority for making the Determination is subsection 23B(9) of the *Therapeutic Goods Act 1989* (“the Act”).

Section 4 – Definitions

This section provides the definitions of certain terms used in the Determination that are not otherwise defined in the Act. This section also notes that a number of expressions used in the Determination, including ‘medicine’ and ‘registered goods’, have the same meaning as in the Act.

Section 5 – Application

This section provides that the Determination applies to medicines of the class specified in paragraph 4(1)(a) of the *Therapeutic Goods (Classes of Therapeutic Goods) Instrument 2018*. These medicines include prescription and other medicines specified in items 1 to 13 of Part 1 of Schedule 10 to the *Therapeutic Goods Regulations 1990*, nasal corticosteroids and metered dose asthma inhalers.

The note to this section highlights that the *Therapeutic Goods (Classes of Therapeutic Goods) Instrument 2018* is a notifiable instrument and is published on the Federal Register of Legislation at www.legislation.gov.au.

Section 6 – Kind of information

This section provides that, for the purposes of subparagraph 23B(2)(d)(i) of the Act, an application for the registration of a medicine mentioned in Schedule 1 to the Determination must be accompanied by the information specified for the medicine in the following documents published by the TGA:

- *CTD Module 1: Administrative information and prescribing information for Australia* (Version 4.3, December 2020); and
- *Mandatory requirements for an effective application* (Version 4.1, June 2022);

as those documents are in force or existing at the commencement of the Determination.

Schedule 1 – Prescription Medicines

This schedule specifies different types of medicine within the class mentioned in section 5 of the Determination, for the purposes of section 6. These types of medicine include, for example, a ‘new chemical entity medicine’ and a ‘new combination medicine’.

Statement of compatibility with human rights

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

Therapeutic Goods (Prescription Medicines—Kind of Information that Must Accompany Application for Registration) Determination 2022

The *Therapeutic Goods (Prescription Medicines—Kind of Information that Must Accompany Application for Registration) Determination 2022* (“the instrument”) is a disallowable legislative instrument and 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

In 2018, the *Therapeutic Goods Amendment (2017 Measures No. 1) Act 2018* (“the Amendment Act”) amended the *Therapeutic Goods Act 1989* (“the Act”) to, among other things, 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. In particular, the Amendment Act introduced measures to require an application for the inclusion of a medicine, biological or medical device in the Register to meet certain preliminary requirements before the Secretary is required to evaluate the application. The Amendment Act also provided the Secretary with the power to refuse an application prior to evaluation if the application does not meet those requirements.

These requirements include that an application has been made in accordance with the appropriate approved form for the relevant class of therapeutic goods and is accompanied by the necessary kind of information needed to evaluate the application. The requirements are designed to enable the effective management of resources by the Department in the evaluation of therapeutic goods, and to create certainty for sponsors as to the appropriate regulatory pathway for their products. A full evaluation process represents a considerable investment in, and use of, Commonwealth resources. Consequently, there are considerable efficiencies to be gained in mandating content and form requirements for applications to provide clarity regarding application requirements, to streamline application and evaluation processes, and to prevent delays in evaluating applications.

Specifically, the Amendment Act introduced new sections 23A and 23B to the Act. Section 23A provides for the Secretary to specify different classes of therapeutic goods, by notifiable instrument, for the purposes of section 23B. Section 23B sets out the preliminary assessment requirements relating to applications for the registration of therapeutic goods, and the listing of medicines under section 26AE of the Act. These requirements include that the application must be accompanied by information that is of a kind determined under subsection 23B(9) (subparagraph 23B(2)(d)(i) of the Act refers), and that the information is in a form determined under subsection 23B(10) (subparagraph 23B(2)(d)(ii) of the Act refers).

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.

Classes of therapeutic goods are specified in the *Therapeutic Goods (Classes of Therapeutic Goods) Instrument 2018* (“the Classes Instrument”), which is made under section 23A of the Act and includes the class ‘prescription and other medicines’.

The instrument is made under subsection 23B(9) of the Act for the purposes of subparagraph 23B(2)(d)(i). It has the effect of determining that an application for the registration of a medicine in the ‘prescription and other medicines’ class (specified in paragraph 4(1)(a) of the Classes Instrument and mentioned in Schedule 1 to the instrument), must be accompanied by the kind of information specified for the particular medicine in the following documents published by the TGA:

- the document titled *CTD Module 1: Administrative information and prescribing information for Australia* (Version 4.3, December 2020); and
- the document titled *Mandatory requirements for an effective application* (Version 4.1, June 2022).

Human rights implications

The instrument engages the right to health in Article 12 of the *International Covenant on Economic, Social and Cultural Rights* (“the ICESCR”). Article 12 of the ICESCR promotes the right of all individuals to enjoy the highest attainable standards of physical and mental health. In *General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12) (2000)*, the United Nations Committee on Economic, Social and Cultural Rights states that health is a ‘fundamental human right indispensable for the exercise of other human rights’, and that the right to health is not to be understood as the right to be healthy, but includes the right to a system of health protection which provides equal opportunity for people to enjoy the highest attainable level of health.

The instrument takes positive steps to promote the right to health by ensuring that there is sufficient information accompanying an application for registration of a prescription or other medicine to enable the application to be processed by the Secretary in an effective and timely manner. The information that must accompany such an application for registration will assist in ensuring the quality, safety and efficacy of these medicines, as well as their timely availability in Australia.

Conclusion

This legislative instrument is compatible with human rights because it promotes the right to health in Article 12 of the ICESCR and otherwise does not raise any other human rights issues.