

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Complementary Medicines—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 and Aged Care (“the Department”).

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 included 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. These 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 to, by notifiable instrument, 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) of the Act, and that the information is in a form determined under subsection 23B(10) of the Act.

Relevantly, subsection 23B(9) 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) 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.

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 ‘complementary medicines’, to which the *Therapeutic Goods (Complementary Medicines—Information that Must Accompany Application for Registration) Determination 2022* (“the Determination”) applies.

The Determination is a legislative instrument made under subsections 23B(9) and (10) of the Act, for the purpose of the application of subparagraphs 23B(2)(d)(i) and (ii) respectively, and specifies

the kind and form of information that must accompany an application for the registration of a complementary medicine.

The Determination repeals and replaces the *Therapeutic Goods (Complementary Medicines—Information that Must Accompany Application for Registration Determination August 2018* (“the former Determination”), principally to update two TGA documents that are incorporated by reference for the purposes of identifying supporting information that an application for the registration of a complementary medicine must be accompanied by.

The former Determination required that an application for the registration of a complementary medicine in the Register must be accompanied by:

- the information required by the document titled *CTD Module 1: registered complementary medicines*, version 8.0, published by the TGA in April 2018; and
- the information required by the document titled *Mandatory requirements for an effective registered complementary medicines application*, version 1, published by the TGA in March 2018.

The Determination replaces the requirement for such an application to be accompanied by information required by the above documents with a requirement that such an application must be accompanied by information of the following kind:

- the information specified for the medicine in the document titled *CTD Module 1: Administrative information for registered complementary medicines, Australian regulatory guidance* (version 1.0, May 2020), published by the TGA, as in force or existing at the commencement of the Determination; and
- the information specified for the medicine in the document titled *Mandatory requirements for an effective registered complementary medicine application, for applications lodged from March 2018* (version 1.1, July 2021), published by the TGA, as in force or existing at the commencement of the Determination.

The main effects of these updates are to reflect current processes for registered complementary medicine applications and the inclusion of a small amount of new information, including for instance in relation to:

- how to respond by letter or email to requests by the TGA for information about their applications if required;
- relying on evaluation reports about such medicines that have been prepared by overseas regulators to allow for reduced evaluation timeframes; and
- requiring applicants to separately enter all ingredients of a complementary medicine for which registration is sought, rather than allowing applicants to enter premixtures of active ingredients by using an allocated number for the premixture.

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 23B of the Act and is freely available on the Federal Registration of Legislation at www.legislation.gov.au.

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

- *CTD Module 1: Administrative information for registered complementary medicines, Australian regulatory guidance* (version 1.0, May 2020);
- *Mandatory requirements for an effective registered complementary medicine application, for applications lodged from March 2018* (version 1.1, July 2021); and
- *General dossier requirements* (version 1.4, July 2018).

The first two documents describe the information that must be submitted to support an application for registration of a complementary medicine under section 23 of the Act, and the third document details the form in which such information must be submitted. Each of these documents is freely available on the TGA website at www.tga.gov.au.

The above four 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* (“the Legislation Act”).

Consultation

The principal effect of the Determination is to reflect current versions of the documents which prescribe the kind of information that must accompany an application for registration. The kinds of information required under the Determination is unchanged from the former Determination.

The two revised documents incorporated into the Determination are published on the TGA website and are currently in use by industry.

In relation to *CTD Module 1: Administrative information for registered complementary medicines, Australian regulatory guidance* (version 1.0, published in May 2020) the Complementary and Over the Counter Medicines Regulatory and Technical Forum (ComTech) (consisting of representatives from Complementary Medicines Australia; Consumer Health Products Australia; ACCORD - representing the hygiene, cosmetic & speciality products industry; and the Association of Therapeutic Goods Consultants) were informed at the ComTech meeting on 4 October 2019 of the restructure of the Australian Regulatory Guidelines for Complementary Medicines to provide a stand-alone document for the purposes of administrative information requirements for applications for the registration of complementary medicines. No objections were received in relation to the proposal. The revised stand-alone document has been used by applicants of registered complementary medicines since its publication in May 2020, with applicants not raising any objections to meeting the requirements specified in the document.

In relation to *Mandatory requirements for an effective registered complementary medicine application, for applications lodged from March 2018* (version 1.1, July 2021), the TGA conducted a public consultation from January to February 2021 on the proposal to streamline how we enter information about premixture ingredient formulations of therapeutic goods into TGA electronic systems when an applicant is seeking market approval. The majority of respondents supported the proposal to cease allocating numbers for new premixture formulations with active ingredients, some stating that it was a sensible removal of redundant administrative processes. The outcomes of the consultation and responses where consent has been given to publish the response is available through the TGA’s consultation hub.

The Office of Impact Analysis advised that an Impact Analysis is not required as the Determination is unlikely to have more than a minor regulatory impact (OBPR22-03750).

Details of the Determination are set out in **Attachment A**.

The Determination is compatible with human rights and freedoms recognised or declared under Part 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 for the purposes of the Legislation Act and commences the day after the it is registered on the Federal Register of Legislation.

Details of the *Therapeutic Goods (Complementary Medicines—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 (Complementary Medicines—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 it is registered on the Federal Register of Legislation.

Section 3 - Authority

This section provides that the legislative authority for making the Determination is subsections 23B(9) and (10) of the *Therapeutic Goods Act 1989* (“the Act”).

Section 4 – Definitions

This section provides the definitions of key terms used in the Determination, including ‘complementary medicine’, ‘Regulations’ and ‘Therapeutic Goods Administration’. This section also notes that some expressions used in the Determination, including ‘medicine’, 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)(b) of the *Therapeutic Goods (Classes of Therapeutic Goods) Instrument 2018*, as it is in force or existing at the commencement of this Determination. The class specified in this paragraph is ‘complementary medicines’.

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 complementary medicine must be accompanied by the information specified for the medicine in the following documents published by the Therapeutic Goods Administration (“the TGA”):

- *CTD Module 1: Administrative information for registered complementary medicines, Australian regulatory guidance* (version 1.0, May 2020); and
- *Mandatory requirements for an effective registered complementary medicine application, for applications lodged from March 2018* (versions 1.1, July 2021);

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

The note to this section highlights that those documents are published at www.tga.gov.au.

Section 7 – Form of information

This section provides that, for the purposes of subparagraph 23B(2)(d)(ii) of the Act, the information that accompanies an application for the registration of a complementary medicine must be contained in an application dossier and in a form consistent with the document titled *General dossier requirements* (version 1.4, July 2018) published by the TGA, as in force or existing at the commencement of the Determination.

The note to this section highlights that the *General dossier requirements* (version 1.4, July 2018) is published at www.tga.gov.au.

Section 8 – Repeals

This section provides that each instrument in Schedule 1 to the Determination is repealed as set out in the applicable items in that Schedule.

Schedule 1 – Repeals

This Schedule provides that the *Therapeutic Goods (Complementary Medicines—Information that Must Accompany Application for Registration) Determination August 2018* is repealed.

Statement of compatibility with human rights

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

Therapeutic Goods (Complementary Medicines—Information that Must Accompany Application for Registration) Determination 2022

This disallowable legislative instrument 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 Amendment (2017 Measures No.1) Act 2018* (“the amendment Act”) amended the *Therapeutic Goods Act 1989* (“the Act”) 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 included 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 of Health and Aged Care 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 a that the application must be accompanied by information that is of a kind determined under subsection 23B(9), and that the information is in a form determined under subsection 23B(10).

Relevantly, subsection 23B(9) of the Act 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 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.

Classes of therapeutic goods are specified in the *Therapeutic Goods (Classes of Therapeutic Goods) Instrument 2018* (“the classes instrument”), which is a notifiable instrument made under section 23A of the Act. The classes instrument includes the class ‘complementary medicines’, to which the *Therapeutic Goods (Complementary Medicines—Information that Must Accompany Application for Registration) Determination 2022* (“the instrument”) applies.

The instrument is a legislative instrument made under subsections 23B(9) and (10) of the Act for the purpose of the application of subparagraphs 23B(2)(d)(i) and (ii) respectively, and specifies the kind and form of information that must accompany an application for the registration of a complementary medicine.

The instrument repeals and replaces the *Therapeutic Goods (Complementary Medicines—Information that Must Accompany Application for Registration Determination August 2018* (“the former instrument”), principally to update two TGA documents that are incorporated by reference for the purposes of identifying supporting information that an application for the registration of a complementary medicine must be accompanied by.

The former instrument required that an application for the registration of a complementary medicine in the Register must be accompanied by:

- the information required by the document titled *CTD Module 1: registered complementary medicines*, version 8.0, published by the TGA in April 2018; and
- the information required by the document titled *Mandatory requirements for an effective registered complementary medicines application*, version 1, published by the TGA in March 2018.

The instrument replaces the requirement for such an application to be accompanied by information required by the above documents with a requirement that such an application must be accompanied by information of the following kind:

- the information specified for the medicine in the document titled *CTD Module 1: Administrative information for registered complementary medicines, Australian regulatory guidance* (version 1.0, May 2020), published by the TGA, as in force or existing at the commencement of the instrument; and
- the information specified for the medicine in the document titled *Mandatory requirements for an effective registered complementary medicine application, for applications lodged from March 2018* (version 1.1, July 2021), published by the TGA, as in force or existing at the commencement of the instrument.

The main effects of these updates are to reflect current processes for registered complementary medicine applications and the inclusion in particular of new information, including for instance in relation to:

- how to respond by letter or email to requests by the TGA for information about their applications if required;
- relying on evaluation reports about such medicines that have been prepared by overseas regulators to allow for reduced evaluation times; and
- requiring applicants to separately enter all ingredients of a complementary medicine for which registration is sought, rather than allowing applicants to enter premixtures of active ingredients by using an allocated number for the premixture.

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 complementary 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.

In addition, the instrument ensures that the process for applying for the registration of a complementary medicine is as efficient, transparent and reliable as possible. The use of a standard form of information will support the right to health by streamlining the application process for sponsors, with flow-on benefits for patients and health practitioners through quicker access to important new medicines in Australia.

Conclusion

This 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.