EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Prescription Medicines—Information Accompanying Applications for Registration) Determination 2021

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 preliminary assessment of applications for the inclusion of therapeutic goods in the Australian Register of Therapeutic Goods ("the Register"). 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 may proceed to evaluation. 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 characterisation of, and 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, 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 requirement that the application 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).

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.

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—Form of Information Accompanying Applications for Registration) Determination 2021* ("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(10) of the Act for the purposes of subparagraph 23B(2)(d)(ii). It has the effect of determining that the information in an application dossier that accompanies an application for the registration of a medicine in the 'prescription and other medicines' class mentioned in Schedule 1, must be in the eCTD format or, in exceptional circumstances, another format with the prior written agreement of the TGA.

eCTD is an international standard formatting style that is used by many comparable overseas regulators. The majority of the sponsors of medicines to which the Determination applies already use the eCTD format. However, a small number continue to use other formats, and section 2 of the Determination (relating to commencement) provides a staggered implementation of the new requirements. The staggered implementation is principally to allow sponsors of certain types of prescription medicines who do not currently use eCTD, additional time (until 1 June 2022) to update their systems and processes.

Consultation

Public consultation occurred during November to December in 2018. The TGA received 22 responses: 19 from sponsors or regulatory consultants, two from industry representative groups, and one from a related software vendor.

All respondents supported mandating the eCTD format for prescription medicines and 95 per cent of respondents supported a staggered implementation approach to the introduction of the proposed new requirement, beginning with those medicines for which applicants were already using the eCTD format. 54 per cent of respondents requested additional time to transition to eCTD, which was accommodated by delaying the commencement of the Determination until 1 November 2021 (and until 1 June 2022 for some medicines, such as new generic medicines).

In early February 2020, the TGA contacted 16 sponsors not currently using the eCTD format to seek their feedback on their current plans to transition to eCTD, and to offer support and guidance. Four responses were received, with three respondents stating that they were currently preparing for a transition to eCTD and would appreciate further advice on the TGA's eCTD implementation plan.

The Office of Best Practice Regulation ("OBPR") advised that this proposal would be unlikely to have more than a minor regulatory impact and determined that a Regulatory Impact Statement (RIS) would not be required (OBPR reference 25620).

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 has a staggered commencement beginning on 1 November 2021.

Attachment A

Details of the *Therapeutic Goods (Prescription Medicines—Information Accompanying Applications for Registration) Determination 2021*

Section 1 – Name

This section provides that the name of the Determination is the *Therapeutic Goods (Prescription Medicines—Information Accompanying Applications for Registration) Determination 2021* ("the Determination").

Section 2 – Commencement

This section provides that sections 1 to 7, and items 1 to 4 of Schedule 1, of the Determination commence on 1 November 2021, and that items 5 to 7 of Schedule 1 commence on 1 June 2022.

Section 3 – Authority

This section provides that the legislative authority for making the Determination is subsection 23B(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 'eCTD', 'new chemical entity medicine' and 'new generic medicine'. 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*.

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 – Form of information

This section provides that, for the purposes of subparagraph 23B(2)(d)(ii) of the Act, the information in an application dossier, that accompanies an application for the registration of a medicine mentioned in Schedule 1, must be in the eCTD format or, if exceptional circumstances exist, another format with the prior written agreement of the Therapeutic Goods Administration.

Schedule 1 – Prescription Medicines

This schedule specifies different types of medicine within the class mentioned in section 4, for the purposes of section 6. These types include, for example, a 'new 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—Information Accompanying Applications for Registration) Determination 2021

The *Therapeutic Goods (Prescription Medicines—Information Accompanying Applications for Registration) Determination 2021* ("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 preliminary assessment of applications for the inclusion of therapeutic goods in the Australian Register of Therapeutic Goods ("the Register"). 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 may proceed to evaluation. 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 characterisation of, and 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 a requirement that the application 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).

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.

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

The instrument to which this statement relates is made under subsection 23B(10) of the Act for the purposes of subparagraph 23B(2)(d)(ii) of the Act. Its purpose is to determine the form in which information in an application dossier that accompanies an application for the registration of a medicine in the 'prescription and other medicines' class is submitted to the Secretary. The medicines to which the instrument relates are those specified in paragraph 4(1)(a) of the *Therapeutic Goods (Classes of Therapeutic Goods) Instrument 2018*) and mentioned in Schedule 1 to the instrument. The form that is determined in the instrument is the eCTD format or, in exceptional circumstances, another format with the prior written agreement of the TGA. eCTD is an international standard formatting style that is used by many comparable overseas regulators.

The majority of the sponsors of medicines to which the instrument applies already use the eCTD format. However, a small number continue to use other formats, and section 2 of the instrument (relating to commencement) provides a staggered implementation of the new requirements. This is principally to allow sponsors of certain types of medicines who do not currently use eCTD additional time (until 1 June 2022) to update their systems and processes.

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 the process for applying for the registration of a prescription or other medicine is as efficient, transparent and reliable as possible. The use of an internationally recognised standard format 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 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.