

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Prescription Medicines—Information Accompanying Applications for Registration) Amendment Determination 2025

The *Therapeutic Goods Act 1989* (“the Act”) provides for the establishment and maintenance of a national system of controls for the quality, safety, efficacy or performance, 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 Act provides for the preliminary assessment of applications for the inclusion of therapeutic goods in the Australian Register of Therapeutic Goods (“the Register”). In particular, the Act requires 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 Secretary may refuse an application prior to evaluation if the application does not meet those requirements.

Section 23B of the Act 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) for a class of therapeutic goods, and that the information is in a form determined under subsection 23B(10) for the class of therapeutic goods. Relevantly, subsection 23B(10) of the Act relevant provides that the Secretary may, by legislative instrument, determine a form of information for the purposes of such applications.

The *Therapeutic Goods (Prescription Medicines—Information Accompanying Applications for Registration) Determination 2021* (“the Principal Determination”) was made under subsection 23B(10) of the Act. It specifies the form requirements for information that accompanies an application for registration of a prescription medicine.

The *Therapeutic Goods (Prescription Medicines—Information Accompanying Applications for Registration) Amendment Determination 2025* (“the Amendment Determination”) amends the Principal Determination to specify updated references to the versions of the electronic Common Technical Document that must be used when submitting an application for registration of a prescription medicine to the TGA.

Background

The Act requires an application for the inclusion of a therapeutic good in the Register to meet certain preliminary requirements before the Secretary may proceed to evaluation. These requirements include that an application has been made in accordance with the appropriate approved form for the relevant class of therapeutic goods, and that it 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. 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.

Relevantly, paragraph 23B(2)(d) of the Act provides that an application under section 23 for registration of therapeutic goods must be accompanied by information that is of a kind determined

under subsection (9) for that class of therapeutic goods, and in a form determined under subsection (10) for that class of therapeutic goods.

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’, which is the class of therapeutic goods to which the Principal 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 Principal Determination has the effect of determining that the information in an application dossier that accompanies an application for the registration of a medicine specified in Schedule 1 to the Principal Determination must be in the electronic Common Technical Document (eCTD) format or, in exceptional circumstances, another format with the prior written agreement of the TGA.

The eCTD format is an international standard formatting style published by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. It is used by many comparable overseas regulators and provides the means for sponsors of medicines to transfer information to regulators as required in an efficient manner, without having to prepare a completely different application for different national regulators. Only module 1 of an application dossier that is in the eCTD format needs to be specific to Australian requirements as set out in the *eCTD AU Module 1 and regional information*.

Purpose

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use has published an updated version of the eCTD format – version 3.2.2. Further, the most recent version of the *eCTD AU module 1 and regional information* that the TGA has published is version 3.2.

The Amendment Determination, which commences on 1 April 2025, replaces the definition of eCTD in section 4 of the Principal Determination to specify updated version numbers of the eCTD format that applicants are required to comply with for all modules of an application dossier. The effect of this is that applicants will need to comply with version 3.2. of the *eCTD AU module 1 and regional information* for Module 1, and version 3.2.2 of the ICH *eCTD Specification* for the rest of their application dossier. The purpose of this is to create international harmonisation and align Australian requirements with more recent international requirements, to reduce the regulatory burden on applicants.

The Amendment Determination also includes a transitional arrangement allowing for a 6-month transition period to comply with the updated eCTD requirements. Under new section 7, applications made before 1 October 2025 can continue to comply with the previous version of the eCTD. However, all applications made from 1 October 2025 will need to comply with the updated versions.

Incorporation by reference

The Amendment Determination incorporates by reference the:

1. *eCTD AU module 1 and regional information* v3.2, which is published by the TGA and available for free on the TGA website (at www.tga.gov.au); and

2. ICH *eCTD Specification* v3.2.2, which is published by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use and available for free on the ICH website (www.ich.org).

These documents are incorporated as in force or existing on 1 April 2025, being the day that the Amendment Determination commences, in accordance with paragraph 14(1)(b) of the *Legislation Act 2003* (“the Legislation Act”).

Consultation

On 13 September 2023, the TGA sent out a request to Medicine Australia, and Generic and Biosimilar Medicines Association for industry participants, for a working group relating to the adoption of the *eCTD AU Module 1 and regional information* v3.2 and ICH *eCTD Specification* v3.2.2. The working group comprised of 16 industry stakeholders with expertise in regulatory affairs and dossier management. Meetings of this working group were held on 12 October, 20 October, 24 October and 1 November 2023. Feedback from participants in the working group regarding the proposed transitional timeframe was incorporated into the amendments and the working group participants were otherwise supportive of the proposal.

Other details

The Office of Impact Analysis (“OIA”) determined that an Impact Analysis was not required on the basis that the proposed amendments to the Principal Determination will improve alignment with current business processes, and be better suited towards industry needs (OIA24-07055).

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

The Amendment 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 Amendment Determination is a disallowable legislative instrument for the purposes of the *Legislation Act 2003*, and commences on 1 April 2025.

Details of the *Therapeutic Goods (Prescription Medicines—Information Accompanying Applications for Registration) Amendment Determination 2025*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods (Prescription Medicines—Information Accompanying Applications for Registration) Amendment Determination 2025* (“the Amendment Determination”).

Section 2 – Commencement

This section provides that the Amendment Determination commences on 1 April 2025.

Section 3 – Authority

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

Subsection 33(3) of the *Acts Interpretation Act 1901* relevantly provides that, where an Act confers a power to make, grant or issue any instrument of a legislative or administrative character, the power shall be construed as including a power exercisable in the like manner and subject to the like conditions (if any) to repeal, rescind, revoke, amend, or vary any such instrument. The Amendment Determination is made in accordance with that provision.

Section 4 – Schedules

This section provides that each instrument that is specified in a Schedule to the Amendment Determination is amended as set out in the applicable items in the Schedule concerned, and that any other item in a Schedule to the Amendment Determination has effect according to its terms.

Schedule 1 – Amendments

This Schedule amends the *Therapeutic Goods (Prescription Medicines—Information Accompanying Applications for Registration) Determination 2021* (“the Principal Determination”).

Item 1– Section 4 (definition of *eCTD*)

This item repeals and replaces the definition of *eCTD* in the Principal Determination, to adopt version 3.2 of the *eCTD AU module 1 and regional information*, and the ICH *eCTD Specification* v3.2.2. Both documents referred to in the new definition are incorporated as in force or existing on 1 April 2025. The note to the new definition of *eCTD* provides details of where these documents are published and how they may be accessed.

Item 2– Section 7

This item provides the transitional arrangements for applications for registration that are in accordance with the *eCTD* format. Applicants may continue to comply with the previous version of the *eCTD* format for applications made before 1 October 2025. All applications made on or after 1 October 2025 must comply with the versions of the *eCTD* format specified in the new definition of *eCTD*.

Statement of Compatibility with Human Rights

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

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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

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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 amends the definition of *eCTD* in section 4 of the Principal Determination, with the effect that applications for registration of a prescription medicine in the Register must comply with updated *eCTD* requirements.

The purpose of this legislative instrument is to improve alignment with current business processes, create international harmonisation for requirements for such applications, ensure Australian-specific requirements are current, and ensure that the requirements are better suited towards the needs of industry. The amendments also support the efficient processing of applications and the evaluation of therapeutic goods. This prevents delays in the evaluation of applications, and supports more timely access to therapeutic goods for Australian patients.

Conclusion

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