

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

I, Nicholas Henderson, as delegate of the Secretary of the Department of Health and Aged Care, make the following determination.

Dated 6 March 2025

Nicholas Henderson

First Assistant Secretary

Medicines Regulation Division

Health Products Regulation Group

Department of Health and Aged Care

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1 Name

 This instrument is the *Therapeutic Goods (Prescription Medicines—Information Accompanying Applications for Registration) Amendment Determination 2025*.

2 Commencement

1. Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

| Commencement information |
| --- |
| Column 1 | Column 2 | Column 3 |
| Provisions | Commencement | Date/Details |
| 1. The whole of this instrument | 1 April 2025. | 1 April 2025 |

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

1. Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

 This instrument is made under subsection 23B(10) of the *Therapeutic Goods Act 1989*.

4 Schedules

 Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

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

1 Section 4 (definition of *eCTD*)

Repeal the definition, substitute:

 ***eCTD*** means the electronic Common Technical Document standard format, including:

 (a) Module 1 in accordance with *eCTD AU module 1 and regional information* v3.2, as in force or existing on 1 April 2025; and

(b) Modules 2 to 5 in accordance with ICH *eCTD Specification* v3.2.2, as in force or existing on 1 April 2025.

Note: The *eCTD AU module 1 and regulation information* v3.2 is published by the TGA on the TGA website at www.tga.gov.au. The ICH *eCTD Specification* v3.2.2. is published by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use and is available at www.ich.org.

2 After section 6

Insert:

**7 Application, savings and transitional provisions**

 This instrument, as in force immediately before the amendments made by the *Therapeutic Goods (Prescription Medicines—Information Accompanying Applications for Registration) Amendment Determination 2025*, continues to apply to applications for registration made before 1 October 2025.