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

Contents

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Note: This table relates only to the provisions of this instrument as originally made.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.

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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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